(a)	**Product Identifier:**	Chlorothiazide Sodium for Injection, USP
(b)	**Product Code:**	25021-305-20, 25021-305-66
	Common/Trade Name:	Sodium Diuril, Chlorothiazide Sodium
	Chemical Name:	6-Chloro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide Monosodium Salt
	Chemical Family:	Diuretic, antihypertensive
(c)	**Product Use:**	Pharmaceutical
	Product Type:	Regulated Prescription Drug
	Container Information:	Vial
(d)	**Distributor:**	Sagent Pharmaceuticals, 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600
(e)	**Emergency Telephone:**	866-625-1618

Section 2 - Hazards Identification

(a)	**Classification:**	Not available.
(b)	**Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):**	Not available.
(c)	**Description of Hazards:**	**Health Hazards:** The chief health hazard associated with overexposures during normal occupational use and handling is irritation of contaminated tissues. **Flammability Hazards:** This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including e.g., carbon oxides, nitrogen oxides, sulfur oxides, sodium oxides, and hydrogen chloride).
(d)	**Unknown Acute Toxicity:**	**N/A**

Section 3 – Composition / Information on Ingredients*

(a) Chemical Name	(b) Common Name / Synonym	Quantity per mL	(c) CAS No.	(d) Impurities / Stabilizing Additives
Chlorothiazide	Chlorothiazide	40.0 mg	58-94-6	N/A
Mannitol	Mannitol	20.0 mg	69-65-8	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s for pH adjustment	1310-73-2	N/A
Water for Injection	Water for Injection	q.s to 1 mL	7732-18-5	N/A
Nitrogen[1]	Nitrogen[1]	A.R	7727-37-9	N/A

* Quantitative Composition of Chlorothiazide Sodium for Injection, USP – 500 mg/Vial Prior to Lyophilization
q.s. = quantity sufficient; A.R = As Required, NA = Not Applicable
1 Quantity sufficient for overlaying of mixing vessel during formulation, filtration and during lyo process

Section 4 - First Aid Measures

Eye Exposure: If product contacts the eyes rinse eyes thoroughly. Minimum flushing is for 15 minutes. If the exposure has resulted in an adverse effect, seek medical attention.

Skin Exposure: Basic hygiene should prevent any problems. If contact with the skin causes irritation, rinse with running water. Remove contaminated clothing, taking care not to contaminate eyes. If an adverse reaction occurs, seek medical attention.

Ingestion: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Maintain an open airway and obtain immediate medical attention.

Inhalation: In unlikely event that inhalation occurs and adverse effect occurs, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

Notes to Physician: Persons developing hypersensitivity reactions to preparations containing Chlorothiazide should receive immediate medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of container label, Product Insert and MSDS to physician or health professional with the affected individual.

Section 5 –Fire-fighting Measures

(a) Extinguishing Media Use extinguishing media appropriate for surrounding fire. Use water, dry chemical, foam, carbon dioxide, halon or an ABC multi-purpose extinguisher.

(b) Hazardous Combustion Products: This product must be substantially pre-heated before ignition can occur. 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.

(c) Special Protective Equipment / Precautions: As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Fire fighters should follow normal fire response procedures consistent with surrounding materials.

Section 6 - Accidental Release Measures

Spill: 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. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with appropriate U.S. Federal, State, and local regulations.

Release to Air: Avoid producing airborne dusts of this product during cleanup. If aerosolized, reduce exposures by ventilating area.

Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling: As with all chemicals, avoid getting this material ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling substance or equipment and containers of this compound. Follow SPECIFIC USE INSTRUCTIONS supplied with compound.

Storage Conditions: Employees must be trained to properly use this product. Ensure vials are properly labeled. Store this product away from incompatible materials. Store at controlled room temperature of 20-25°C (68ºF-77°F) according Package Labeling instructions.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Chlorothiazide	OSHA	PEL	TWA mg/m^3 50 mppcf or 15 (Total Dust) 15 mppcf or 5 (Respirable Fraction)
	ACGIH	TLV	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
Sodium Hydroxide	OSHA	PEL	NE
	ACGIH	TLV	NE

(b) Engineering Controls

Ventilation: Use with adequate ventilation. Follow standard medical product handling procedures.

(c) Individual Protection Measures

Respiratory Protection:	Under normal use, respirators are not required.
Eye Protection:	For situations in which airborne dusts or splashes of reconstituted product may be generated, wear safety glasses.
Skin Protection:	For situations in which prolonged skin contact is anticipated, double glove, using natural rubber, neoprene, or nitrile gloves. Wash hands before putting on gloves and after removing gloves.
Other Protective Equipment:	During patient administration, use of lightweight cotton gown or other medical attire is recommended.
Additional Exposure Precautions:	Wash hands following use. No eating, drinking, or smoking while handling this product.

Section 9 - Physical and Chemical Properties		
(a)	**Appearance**	Odorless, white powder/cake
(b)	**Odor**	No Odor
(c)	**Odor Threshold**	Not Applicable
(d)	**pH**	9.2 – 10.0 after reconstitution
(e)	**Melting Point:**	Not established
(f)	**Initial Boiling Point:**	Not established
(g)	**Flash Point**	Not established
(h)	**Evaporation Rate:**	Not established
(i)	**Flammability**	Not available
(j)	**Upper Lower Flammability or Explosion Limits**	Not available
(k)	**Vapor Pressure:**	Not applicable
(l)	**Vapor Density:**	Not available
(m)	**Relative Density**	Not available
(n)	**Solubility(ies)**	Soluble in water
(o)	**Partition Coefficient: n-octanol/water**	Not available
(p)	**Auto-ignition Temperature**	Not available
(q)	**Decomposition Temperature**	Not available
(r)	**Viscosity**	Not available

Section 10 - Stability and Reactivity		
(a)	**Reactivity**	Not available
(b)	**Chemical Stability**	This product is stable when properly stored per label instructions.
(c)	**Possibility of Hazardous Reactions**	Hazardous polymerization will not occur.
(d)	**Conditions to Avoid**	Avoid heat, light, and contact with incompatible chemicals.

(e)	**Incompatible Materials**	This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.
(f)	**Hazardous Decomposition Products**	If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, sulfur oxides, sodium oxides, and hydrogen chloride).

Section 11 - Toxicological Information		
(a)	**Likely Routes of Exposure**	Ingestion, Inhalation, skin, eye
(b)	**Symptoms related to the physical, chemical and toxicological characteristics**	The health hazard information provided below is pertinent to medical employees using this product in an occupational setting: **Acute Toxicity - Dermal**: Not determined **Acute Toxicity - Inhalation**: Not determined. Inhalation of airborne dusts may temporarily irritate the respiratory system. **Dermal Irritation**: Not irritating **Sensitization**: Not determined **Skin Absorption**: Not determined **Eye Irritation**: Eye contact may cause mechanical irritation.
(c)	**Delayed and immediate effects and also chronic effects from short and long term 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.

		Target Organs: Blood system, metabolic system, kidneys. **Other Potential Health Effects-Therapeutic Doses:** Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included the following: 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.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Chlorothiazide	LD_{50}	Oral	Rat	10gm/kg
Chlorothiazide	LD_{50}	Oral	Mouse	8 gm/kg

(e) Hazardous Chemical Listings

NTP: No IARC: No OSHA: No NIOSH Listing: No

Section 12 - Ecological Information		
(a)	**Ecotoxicity**	Not available
(b)	**Persistence and degradability**	The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials.
(c)	**Bioaccumulative potential**	Not available
(d)	**Mobility in soil**	Not available

(e)	**Other Adverse Effects**	Effect of Material on Plants or Animals: This product may be harmful to contaminated plant and animal life, especially in large quantities. Effect of Chemical on Aquatic Life: 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.

Section 13 - Disposal Considerations

Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations. Incineration is recommended.

Section 14 - Transport Information		
(a)	**UN Number**	Not applicable
(b)	**UN Proper Shipping Name**	Not applicable
(c)	**Transport Hazard Class(es)**	Not applicable
(d)	**Packing Group**	Not applicable
(e)	**Environmental Hazards**	Not available
(f)	**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)**	Not available
(g)	**Special Precautions**	Not applicable

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA: Not on this list

CERCLA: Not on this list

SARA 302: Not on this list

SARA 313: Not on this list

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Sagent Pharmaceuticals
1901 N. Roselle Rd, Suite 450
Schaumburg, IL 60195
847-908-1600

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application

NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System