

SAFETY DATA SHEET

 Date: 01/22/2019

Generic Name: Hydrochlorothiazide Capsules, USP 12.5mg

 Brand Equivalent: Microzide

SECTION 1: IDENTIFICATION	
Product Name	Hydrochlorothiazide Capsules, USP 12.5mg
Active substance	Hydrochlorothiazide USP (CTX)
Synonyms	N/A
Formula	C ₇ H ₈ ClN ₃ O ₄ S ₂
Intended Use	Diuretic
Chemical Name	6-chloro-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Physical hazards	Not classified.
Health hazards	Not classified.
OSHA hazard(s)	Not classified.
Symbol	None
Signal word	None.
Hazard statements	This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
Precautionary statements	Observe good industrial hygiene practices.
Prevention	Wash hands after handling.
Response	Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F).
Storage	Dispose of contents/container in accordance with local/regional/national/international regulations. Incineration of waste at an approved USEPA incinerator is recommended.
Disposal	
Hazard(s) not otherwise classified (HNOC)	None known.

3. Composition/Information on ingredients		
Components	CAS-No	Concentration (%w/w)
Hydrochlorothiazide, USP*	58-93-5	8.92%
Lactose Monohydrate, NF (Super Tab 11 SD)	63-42-3	*
Corn Starch NF (400L - Modified Food Starch)	9005-25-8	*
Colloidal Silicon Dioxide NF (Aerosil 200 Pharma)	7631-86-9	*
Magnesium Stearate, NF	557-04-0	*

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES	
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Inhalation	If dust from the material is inhaled, remove the affected person immediately to fresh air. Call a physician if symptoms develop or persist
Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	In clinical trials, no unexpected adverse events were observed. Most adverse experiences were mild in intensity and transient in nature and did not require discontinuation of therapy. Persistent dry cough has been associated with ACE-inhibitor use.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. HANDLING AND STORAGE	
Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Wash hands thoroughly after handling
Conditions for safe storage, including any incompatibilities	Store at 25°C (77°F); excursions permitted to 15 - 30 °C (59 - 86 °F). Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/Personal protection	
Appropriate engineering controls	Ventilation should be matched to conditions.
Respiratory Protection	None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. Contact a health and safety professional or manufacturer for specific information
Eye/face protection	None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.
Hand protection	For consumer use, no unusual precautions are necessary.
Other	None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
<i>Appearance</i>	Opaque light blue colored cap and Opaque light blue colored body imprinted "SG" on cap and "146" on body with black ink.
Physical State	Solid
Color	White
Form	Capsule
<i>Odour</i>	
Odour	Not available
Odor Threshold	Not available
pH	Not available
<i>Other information</i>	
Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	very slightly soluble
Specific Gravity/ Relative Density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available
<i>Thermal/Stability properties</i>	
Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	Not available
<i>Vapor Properties</i>	
Vapor Density	Not available

Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. Stability and Reactivity	
Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Hazardous Decomposition products	Carbon oxides.
Incompatible materials	Strong oxidizing agents.

11. Toxicological Information	
Inhalation	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.
Skin contact	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust or powder may irritate the skin.
Eye contact	Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Dust may irritate the eyes.
Ingestion	Ingestion may cause irritation and malaise.
Symptoms related to the physical, chemical and toxicological characteristics	In clinical trials, no unexpected adverse events were observed. Most adverse experiences were mild in intensity and transient in nature and did not require discontinuation of therapy. Persistent dry cough has been associated with ACE-inhibitor use.
Acute toxicity	May be harmful if swallowed in large quantities.
Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA
Reproductive Toxicity	Due to lack of data the classification is not possible
Developmental Toxicity	Due to lack of data the classification is not possible
Pharmacokinetics/ Toxicokinetics	Due to lack of data the classification is not possible
Other Toxicity Information	Due to lack of data the classification is not possible

12. Ecological Information	
Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available
Mobility in soil	Not available
Other adverse effects	Not available

13. Disposal considerations	
Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information	
DOT	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not available.

15. Regulatory Information	
US federal regulations	This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use. Over-the-counter drugs in their solid final form (e.g. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous. OSHA GHS: GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories	Immediate Hazard - No Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	Not listed.
SARA 311/312 Hazardous chemical	Yes
SARA 313 (TRI reporting)	Not regulated.

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	
Revision	01
Disclaimer	The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.