SAFETY DATA SHEETS

This SDS packet was issued with item:

078951116

N/A

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Product Name: Acetazolamide Tablets USP **Product No.:** 125 mg: 51672-4022
250 mg: 51672-4023

Distributor: Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive, Hawthorne, New York 10532
Telephone: 1-888-TARO-USA

Recommended Use: For adjunctive treatment of: edema due to congestive heart failure; drug-induced edema; centrencephalic epilepsies (petit mal, unlocalized seizures); chronic simple (open-angle) glaucoma, secondary glaucoma, and preoperatively in acute angle-closure glaucoma where delay of surgery is desired in order to lower intraocular pressure.

Restrictions on Use: Acetazolamide therapy is contraindicated in situations in which sodium and/or potassium blood serum levels are depressed, in cases of marked kidney and liver disease or dysfunction, in suprarenal gland failure, and in hyperchloremic acidosis. It is contraindicated in patients with cirrhosis because of the risk of development of hepatic encephalopathy. Long-term administration of acetazolamide is contraindicated in patients with chronic non-congestive angle-closure glaucoma since it may permit organic closure of the angle to occur while the worsening glaucoma is masked by lowered intraocular pressure.

Substance Class: Sulfonamide

Formula: $C_4H_6N_4O_3S_2$

M.W.: 222.25

SECTION 2: HAZARD(S) IDENTIFICATION

Physical Hazards: Not classified.

Health Hazards:		
	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A

OSHA Hazard(s): Not classified.

Label Elements

Signal Word: Warning

Hazard Statement: Causes skin irritation. Causes serious eye irritation.

Precautionary Statement

Prevention: Wash thoroughly after handling. Wear protective gloves. Wear eye/face protection.

Response: If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Disposal: Not available.

Hazard(s) Not Otherwise Classified (HNOC): Not classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient:	Acetazolamide	CAS#: 59-66-5
Inactive Ingredients:	Corn starch, gelatin, glycerin, lactose monohydrate, magnesium stearate, purified water, sodium starch glycolate and talc.	

SECTION 4: FIRST-AID MEASURES

Inhalation: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin Contact: Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye Contact: Rinse with water. Get medical attention if irritation develops and persists.

Ingestion: Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most Important Symptoms/Effects, Acute and Delayed: Irritant effects.

Indication of Immediate Medical Attention and Special Treatment Needed: Treatment of overdose should be symptomatic and supportive. Administer activated charcoal with sorbitol to decrease absorption. For acidosis, administer sodium bicarbonate. Monitor fluid and electrolyte status. Correct fluid and electrolyte disturbances. Hemodialysis may be of benefit. (Poisindex)

General Information: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is

1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO_2.

Unsuitable Extinguishing Media: None known.

Specific Hazards Arising From the Chemical: No unusual fire or explosion hazards noted.

Special Protective Equipment and Precautions for Firefighters: Wear suitable protective equipment.

Fire-Fighting Equipment/Instructions: Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific Methods: Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 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. Avoid inhalation of dust from the spilled material. 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. Clean surface thoroughly to remove residual contamination.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for Safe Storage, Including Any Incompatibilities: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Biological Limit Values: No biological exposure limits noted for the ingredient(s).

Exposure Guidelines: No exposure standards allocated.

Appropriate Engineering Controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual Protection Measures, Such As Personal Protective Equipment

Eye/Face Protection: Safety glasses with sideshields 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.

Skin Protection

Hand Protection: 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 nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other: For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory Protection: 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).

Thermal Hazards: Not available.

General Hygiene Considerations: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point: 496.4 – 500.9°F (258-260.5°C) (decomposes)

Solubility in Water: Very slightly soluble; sparingly soluble in practically boiling water

Appearance:
125 mg: White, round tablet, scored on one side, with “T52” engraved on the other side

250 mg: White, round tablet, cross scored on one side, with “T53” engraved on the other side

Odor: Odorless

SECTION 10: STABILITY AND REACTIVITY

Reactivity: No reactivity hazards known.

Chemical Stability: Material is stable under normal conditions.

Possibility of Hazardous Reactions: No dangerous reaction known under conditions of normal use.

Conditions to Avoid: None known.

Incompatible Materials: Strong oxidizing agents. Peroxides. Isocyanates. Amides. Phenols. Alkali metals. Sulfides.

Hazardous Decomposition Products: NOx. SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure

Ingestion: Based on available data, the classification criteria are not met.
Inhalation: Due to lack of data the classification is not possible.
Skin Contact: Causes skin irritation.
Eye Contact: Causes serious eye irritation.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics: Numbness, pain, tingling, or weakness in hands or feet. Increased urination. Fatigue. Depression. Gastrointestinal disturbances. Loss of appetite. Weight loss. Taste perversion. Skin rash. Hair loss. Nearsightedness. Hearing problems.

Cross Sensitivity: Persons sensitive to antibacterial sulfonamides, thiazide diuretics, other sulfonamide-derivative diuretics, or other carbonic anhydrase inhibitors may be sensitive to this material also.

Medical Conditions Aggravated By Exposure: Chronic angle-closure glaucoma. Diabetes. Lung disease. Addison's disease. Adrenal insufficiency. Hyperchloremic acidosis. Liver impairment. Kidney impairment. Electrolyte imbalance.

Acute Toxicity

Product	Species	Test Results

Acetazolamide (CAS 59-66-5)

Acute

Oral

LD50	Mouse	4300 mg/kg
	Rat	15 - 30 g/kg

Skin Corrosion/Irritation: Causes skin irritation.

Serious Eye Damage/Eye Irritation: Causes serious eye irritation.

Respiratory Sensitization: Due to lack of data the classification is not possible.

Skin Sensitization: Due to lack of data the classification is not possible.

Germ Cell Mutagenicity: Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity:

Bacterial assay

Result: Negative (with or without activation).

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.

SECTION 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.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Instructions: Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local Disposal Regulations: Not available.

Hazardous Waste Code: Not available.

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.

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.

SECTION 14: TRANSPORT INFORMATION

DOT: Not regulated as a hazardous material by DOT.

IATA: Not regulated as a dangerous good.

Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: No information available.

SECTION 15: REGULATORY INFORMATION

U.S. Federal Regulations: CERCLA/SARA Hazardous Substances - Not applicable. All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard Categories: Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely Hazardous Substance: No

SARA 311/312 Hazardous Chemical: No

Other Federal Regulations

Safe Drinking Water Act (SDWA): Not regulated.

Food and Drug Administration (FDA): Not regulated.

U.S. State Regulations: Warning: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

SECTION 16: OTHER INFORMATION

Contact: Taro Pharmaceuticals U.S.A., Inc., Regulatory Affairs Department
3 Skyline Drive, Hawthorne, NY 10532

Preparation and/or Revision Date: October 2016

D I S C L A I M E R

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals assumes no responsibility for the use of this information.