



Material Safety Data Sheet

Acetazolamide

Effective Date: 03-11-2009 Review Date: N/A

Section 1: Chemical Product and Company Identification

Product Name: AcetaZOLAMIDE for Injection USP (500 mg/10ml vial)

Emergency Call CHEMTREC: 800-424-9300

Chemical Names: N-(5-(sulfamoyl-1,3,4-thiadiazol-2yl)-acetamide

CAS Number: 59-66-5

RTECS #: AC8225000

Trade Name: Diamox®

Formula: C₄H₆N₄O₃S₂

M.W.: 222.24

Distributor: X-Gen Pharmaceuticals
PO Box 445
Big Flats, NY 14814

Indication: 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.

Technical Assistance: 607-562-2700

Emergency Call CHEMTREC:
800-424-9300

Section 2: Composition Information

<u>Principle Components</u>	<u>Composition</u>	<u>OSHA PEL</u>
Acetazolamide	100%	None

Sodium Hydroxide and or Hydrochloric Acid if necessary for pH adjustment.

AcetaZOLAMIDE for Injection is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

Section 3: Hazards Identification

Routes of Entry: Primary occupational exposure routes are via inhalation, absorption, or ingestion.

Health Hazard (Acute & Chronic): AcetaZOLAMIDE is a drug used for the treatment of edema in congestive heart failure. It may cause allergic reactions in persons sensitive to antibacterial sulfonamides, thiazide diuretics, or other sulfonamide derived diuretics. Laboratory tests have shown Acetazolamide to be teratogenic in animals.

Carcinogenicity: NTP: No **IARC Monograph:** No **OSHA Regulated:** No

Signs & Symptoms of Exposure: Gastrointestinal disturbances, vomiting, diarrhea, drowsiness or confusion may result. May cause an allergic reaction or irritation to eyes, nose,

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Section 3: Hazards Identification Continued

or respiratory tract. Fever, rash, ringing in ears, loss of appetite, tingling feeling in extremities may also occur.

Medical Conditions Generally Aggravated by Exposure: Persons with kidney or liver disease and persons who are allergic to sulfonamides.

Section 4: First Aid Measures

Eye Exposure: Check for and remove any contact lenses. Flush eyes with large amounts of water for 15 or more minutes. Seek medical attention

Skin Exposure: Wash skin with cool, soapy water for 15 minutes.

Ingestion: If ingestion occurs, induce vomiting immediately and seek medical attention from a physician immediately. Never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek medical attention immediately. If necessary, provide artificial respiration.

Overdose in humans is unlikely to occur since Acetazolamide is remarkably non-toxic as shown in animal testing. Treatment of overexposure should be symptomatic and supportive.

Section 5: Fire Fighting Measures

Flash Point: Not applicable **LEL:** Not applicable **UEL:** Not applicable

Flammable Limits: Not applicable

Extinguisher Media: Use water or type ABC multi-purpose extinguisher.

Special Fire Fighting Procedure: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus to avoid smoke inhalation. Product is not expected to present a fire hazard concern.

Unusual Fire and Explosion Hazards: None

Section 6: Accidental Release Measures

Release to land: Wet acetazolamide with water and absorb with absorbent materials and dispose of according to applicable local, state, and federal regulations.

Release to air: If dust is generated, wear a disposable dust respirator (N95) and reduce exposures by ventilating the area. Clean up spill immediately.

Release to water: Refer to local water authority; drain disposal is not recommended.

Section 7: Handling and Storage

Wear latex or nitrile gloves, safety glasses and a disposable dust mask (N95), wear protective coveralls and shoe covers for large spills.

Waste Disposal Method: Incineration in an approved/permitted incinerator is recommended. Refer to applicable local state and federal laws.

Precautions: Store in a cool dry place. (See USP CRT storage conditions)

Section 8: Exposure Controls / Personal Protection

Respiratory Protection: Under normal use, respirators are not required. If dusts are generated, use a disposable dust mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Ventilation: Handle product in a well ventilated area.

Protective Gloves: Nitrile or Latex.

Eye Protection: Safety glasses

Other Protective Clothing or Equipment: Lab coat

Work hygiene practices: Wash hands following use; no eating, drinking, or smoking while handling product.

Section 9: Physical and Chemical Properties

Physical State: Solid

Specific Gravity: Not applicable

Appearance and Odor: White to yellowish crystalline powder with no odor.

Melting Point: 260.5°C

Evaporation rate: Not available

Boiling Point: Not applicable

Solubility in water: Very soluble

Vapor density: Not applicable

pH: 9.2

Section 10: Stability and Reactivity

Stability: Stable

Incompatibility (Materials to Avoid): Acids and strong oxidizers

Hazardous Decomposition or Byproducts: May emit toxic fumes of sulfur dioxides and nitrogen oxides when burned. As with any burning material, carbon monoxide and carbon dioxide or other toxic gasses may be produced.

Hazardous Polymerization: Not known to occur.

Conditions to Avoid: Store away from acids and oxidizers.

Section 11: Toxicological Information

Routes of Entry: Absorbed through skin. Eye contact. Inhalation.

Chronic Effects on Humans:

DEVELOPMENTAL TOXICITY: Classified development toxin [POSSIBLE]. May cause damage to the following organs: kidneys.

LD₅₀ rat, intraperitoneal = 2750 mg/kg

LD₅₀ mouse, intravenous = 3mg/kg

LD₅₀ mouse, oral = 4300 mg/kg

LD₅₀ mouse, subcutaneous = 3mg/kg

TD_{LO} man, oral = 54 mg/kg

LD₅₀ mouse, intraperitoneal = 1175 mg/kg

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LD₅₀ dog, intravenous =>2 mg/kg

LD₅₀ guinea pig, subcutaneous =>1500mg/kg

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Health Effects of Chemical Substances (RTECS).

Section 12: Ecological Information

Information is not currently available on the environmental impact of acetazolamide. Handle in a manner that prevents spills or releases to the environment.

Section 13: Disposal Information

Dispose of by incineration at an approved/permitted incinerator by local, state and federal regulations.

Section 14: Transport Information

Acetazolamide is not a DOT Hazardous Material.

Acetazolamide is not a marine pollutant.

Section 15: Regulatory Information

Federal and State Regulations:

California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute: Acetazolamide

TSCA 8(b) inventory: Acetazolamide

Other Regulations: EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

Other Classifications:

WHMIS (Canada): Not controlled under WHMIS (Canada).

DSCL (EEC): R36/38- Irritating to eyes and skin. R61- May cause harm to the unborn child.

HMIS (U.S.A.):

National Fire Protection Association (U.S.A.):

Health Hazard: 2

Health: 2

Fire Hazard: 1

Flammability: 1

Reactivity: 0

Reactivity: 0

Personal Protection: E

Specific hazard: N/A

Protective Equipment: Gloves, Lab coat, Dust respirator. Be sure to use an approved certified respirator or equivalent. Safety glasses.

SARA 313 listed? No **CERCLA listed?** No **RCRA listed?** No

AcetaZOLAMIDE is listed on section 8(b) of EPA's TSCA Chemical Inventory.

Section 16: Other Information

Use of this product should be through or under the direction of a physician. This MSDS does not address therapeutic use of this material.

The information is believed to be accurate and represents the best information currently available to us. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use.

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