



300 Northfield Road
 Bedford, OH 44146
 Telephone: (440) 232-3320
 -or- (800) 562-4797

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Sterile Acetazolamide Sodium, USP (500mg/10ml vial)
Chemical Names: Acetamide, N-[5-(aminosulfonyl)-1,3,4-thiadiazol-2-yl]-
Synonyms: Diamox®, Acetemox
Manufacturer's Name: BEN VENUE LABORATORIES, INC.
Address: 300 NORTHFIELD ROAD
 BEDFORD, OH 44146
Emergency Telephone Number: Chemtrec: 1(800)424-9300
Telephone Number for Info.: (440)232-3320 -or- (800)562-4797
Medical Emergency: Professional Services 1(800)521-5169
Date Prepared: June 29, 1995
Date Revised: August 17, 2001

Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Acetazolamide	100%	59-66-5	NONE	NONE	5 mg/ m ³

Sodium Hydroxide and/or Hydrochloric Acid if necessary for pH adjustment
 Acetazolamide is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

Section III - HEALTH HAZARD DATA

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 derivative diuretics. Laboratory tests have shown Acetazolamide to be teratogenic in animals
Carcinogenicity: NTP? NO IARC Monographs? NONE
 OSHA Regulated? NO
Signs & Symptoms of Exposure: Acetazolamide is used to control fluid secretion in congestive heart failure, glaucoma and certain convulsive disorders. Gastrointestinal disturbances, vomiting, diarrhea, drowsiness or confusion may result. May cause an allergic reaction or irritation to eyes, nose, 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.

BVL Hazard Category: 2

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large amounts of water for 15 or more minutes.

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 V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): Not applicable **LEL:** Not Applicable **UEL:** Not Applicable

Flammable Limits: Not applicable

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

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

Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

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

Release to air: If dust is generated, wear a disposable dust/mist 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 VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above.

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

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

Precautions to be taken in handling and storing: Store vials at 59°- 86°F (15-° 30°C).

Other Precautions: None

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required. If dusts are generated, use a disposable dust/mist respirator (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/Hygienic Practices: Wash hands following use; no eating, drinking, or smoking while handling product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid

Specific Gravity: Not applicable

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

Melting Point: Not available

Boiling Point: Not applicable

Evaporation Rate: Not applicable

Vapor Pressure: Not applicable

Solubility in Water: Slightly soluble

Vapor Density: Not applicable

pH: 9.2

Section X - STABILITY AND REACTIVITY DATA

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 gases may be produced.

Hazardous Polymerization: Not known to occur

Conditions to Avoid: Store away from acids and oxidizers

Section XI - TOXICOLOGICAL INFORMATION

For Acetazolamide:

LD₅₀ rat, intraperitoneal = 2750 mg/kg

LD₅₀ mouse, intravenous = 3 mg/kg

LD₅₀ mouse, oral = 4300 mg/kg

LD₅₀ mouse, subcutaneous = 3 mg/kg

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

LD₅₀ mouse, intraperitoneal = 1175 mg/kg

LD₅₀ dog, intravenous = >2 mg/kg

LD₅₀ guinea pig, subcutaneous = >1500 mg/kg

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

Section XII - ENVIRONMENTAL IMPACT INFORMATION

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

Section XIII - DISPOSAL INFORMATION

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

Section XIV - TRANSPORTATION INFORMATION

Sterile Acetazolamide Sodium is not a DOT Hazardous Material.
Acetazolamide is not a Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO

CERCLA listed?: NO

RCRA listed?: NO

Acetazolamide is listed on Section 8(b) of EPA's TSCA Chemical Inventory

Listed on the California Proposition 65 as Code D

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician.
This MSDS does not address therapeutic use of this material.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.

The information provided is believed to be complete and accurate. It is the user's responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.