



Safety Data Sheet

AcetaZOLAMIDE for Injection, USP

Section 1: Chemical Product and Company Identification

Product Name: AcetaZOLAMIDE for Injection, USP

Chemical Name(s): N-(5 SULFAMOYL-1, 3, 4-THIADIAZOL-2YL) Acetamide.

Synonym: Acetazolamide.

CAS Number: 59-66-5

RTECS #: AC8225000

Trade Name: *Diamox*

Chemical Formula: $C_4H_6N_4O_3S_2$



Health	2
Fire	0
Reactivity	0
Personal Protection	E

Contact Information:

X-GEN Pharmaceuticals, Inc.

PO Box 445, Big Flats, NY 14814

Technical Assistance: 607-562-2700

Online Assistance: www.x-gen.us

Emergency phone number:

National Poison Control

1-800-222-1222

**For information regarding recommended uses and restrictions on usage refer to the product package insert.

Section 2: Hazard Identification

Hazard pictograms (GHS-US):



Potential Acute Health Effects: Hazardous in case of inhalation. Slightly harmful in case of skin contact (irritant), of eye contact (irritant).

Potential Chronic Health Effects: AcetaZOLAMIDE is a drug used for the treatment of edema in congestive heart failure. It may cause allergic reactions in persons sensitive to the antibacterial sulfonamides, thiazide diuretics, or other sulfonamide derived diuretics.

Carcinogenic Effects: This material is not considered to be a carcinogen by IARC, NIP or OSHA.

Mutagenic Effects: Not available

Teratogenic Effects: Laboratory tests have shown AcetaZOLAMIDE to be teratogenic in animals.

Developmental Toxicity: Classified development toxin (possible). The substance may be toxic to kidneys. Repeated or prolonged exposure to the substance can produce target organ damage.

Adverse effects: Not available

Section 3: Composition and Information on Ingredients

Principle Components:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Acetazolamide	59-66-5	100

Section 4: First Aid Measures

General: 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 exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Skin contact: In case of contact, immediately wash skin with plenty of water. Cover the irritated skin with an emollient. Remove contaminated clothing and shoes. Wash clothes and thoroughly clean shoes before reuse. Seek medical attention immediately.

Eye contact: Check for and remove any contacts lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Seek medical attention immediately.

Ingestion: DO NOT induce vomiting unless directed to do so by a medical professional. Never give anything by mouth to an unconscious person. Loosen tight clothing such as tie, collar and/or belt. Seek medical attention immediately.

Notes to physician: Seek product package insert for complete information.

Overdose Treatment: Treatment of overdose should be symptomatic and supportive. Administer activated charcoal with sorbitol to decrease absorption. For acidosis, administer sodium bicarbonate. Monitor fluids and electrolyte status. Correct fluid and electrolyte disturbance. Hemodialysis may be of benefit.

Section 5: Fire Fighting Measures

Flammability of the product: May combust at high temperatures.

Combustion Products: These products are carbon oxides (CO, CO²), sulfur oxides (SO², SO³).

Unusual Fire and Explosion Hazards: Product is not expected to present a fire hazard.

Extinguishing Media and instruction:

Small fire: Use DRY chemical powder. **Large fire:** Use water spray, fog or foam. May use type ABC multi-purpose extinguisher. DO NOT use water jet.

Protective equipment & precautions for firefighters: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

Special remarks on fire hazard: Not available

Special remarks on explosion hazard: Not available

Section 6: Accidental Release Measures

Release to land:

Small Spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.

Large Spill: Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum with caution to avoid generation of dust during clean-up. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

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

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

Protective equipment: Keep unnecessary personnel away. Wear latex or nitrile gloves, safety glasses, and a disposable dust mask (N95), wear protective coveralls and shoe covers for spills.

Section 7: Handling and Storage

Handling: As a general rule, when handling AcetaZOLAMIDE for Injection, USP, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material.

Keep locked up. Keep away from heat, sources of ignition and oxidizing agents. Empty containers pose a fire risk, evaporate the residue under a fume hood. DO NOT ingest. DO NOT breathe dust. Wear suitable protective clothing. Use only in accordance with directions.

Storage: Keep container tightly closed. Keep container in a cool, dry, well ventilated area (see USP CRT storage conditions). Protect from light and store at controlled room temperature 20° - 25°C (68° - 77°F). Refer to label instructions to ensure product integrity.

Incompatibilities: Keep away from strong oxidizing agents.

Section 8: Exposure Controls / Personal Protection

Engineering Controls: Use process enclosure, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generates dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protection: Safety glasses. Lab coat. Gloves. Dust respirator. Be sure to use an approved/certified respirator or equivalent. **In case of Large Spill:** Splash goggles. Full suit. Dust respirator. Boots. Gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

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

Exposure limit: Not available

Section 9: Physical and Chemical Properties

Physical appearance: Solid powder.

Color: White to yellowish.

Molecular Weight: 222.25 g/mole

Taste: Not available

Odor: Odorless

Odor Threshold: Not available

pH: 9.0 – 10.0

Melting Point: 260°C (500°F)

Freezing Point: Not available

Boiling Point: Not available

Flash Point: Not available

Evaporation rate: Not available

Flammability: Not available

Upper Flammable Limit: Not available

Lower Flammable Limit: Not available

Vapor Pressure: Not available

Vapor Density: Not available

Relative density: Not available

Partition Coefficient: Not available

Auto-Ignition Temperature: Not available

Decomposition Temperature: Not available

Viscosity: Not available

Dispersion Properties: Partially dispersed in methanol. Very slightly dispersed in cold water, n-octanol, and acetone. Is NOT dispersed in hot water, diethyl ether.

Solubility: Soluble in water. Readily soluble in 1N Sodium Carbonate solution; slightly soluble in ethanol and in acetone; soluble in dilute solutions of alkali hydroxides; insoluble in chloroform, in diethyl ether and in carbon tetrachloride.

Section 10: Stability and Reactivity

Reactivity: Stable under normal conditions.

Chemical stability: Stable. No dangerous reactions are known to occur under conditions of normal use.

Possibility of hazardous reaction: Not available

Conditions to avoid: Store away from acids and oxidizers.

Incompatible materials: Reactive with acids and strong oxidizing agents. Peroxides. Isocyanates. Amides. Phenols, Alkali metals. Sulfides.

Hazardous decomposition products: May emit irritating and/or toxic fumes of sulfur dioxides and nitrogen oxides when burned. As with any burning material, carbon monoxide and carbon dioxide or other gases may be produced.

Corrosivity: Non-corrosive in presence of glass.

Polymerization: Not known to occur.

Section 11: Toxicological Information

Routes of exposure: Absorbed through skin, eye contact, inhalation and ingestion.

Symptoms:

Short term: Hazardous in cases of inhalation. Slightly hazardous in case of skin contact (irritant). **Long**

term: May cause damage to the following organs: Kidneys.

Reproductive toxicity: Due to lack of data the classification is not possible. Reproductive studies in animals yield mixed results.

FDA Pregnancy Category: C

Toxicity to animals:

Oral Rat: LD50: 15-30g/kg

Oral Mouse: LD50: 4300mg/kg

Measures of toxicity: Not available

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

Section 12: Ecological Information

Ecotoxicity: Not available

Bioaccumulation potential: Not available

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The product itself and its products of degradation are not toxic.

Section 13: Disposal Information

Waste classification: Non-Hazardous

Waste from residues/unused products: Dispose of waste in accordance with all applicable federal, state and local laws.

Waste Disposal: Dispose of waste in accordance with all applicable federal, state and local laws.

Section 14: Transport Information

DOT Classification: Not a DOT controlled material (United States).

UN Number: Not available

UN Shipping name: Not available

Transport hazard class: Not available

Packing Group: Not available

Environmental hazard: Not available

Transport in bulk: Not available

Special precautions needed with transport: Not available

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.

AcetaZOLAMIDE TSCA 8(b) inventory: AcetaZOLAMIDE

Other Regulations: EU EINECS List: 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.):
Health Hazard: 2
Fire Hazard: 0
Reactivity: 0
Personal Protection: E

National Fire Protection Association (U.S.A.):
Health: 2
Flammability: 0
Reactivity: 0

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

Section 16: Other Information

References: Not available
Created: 1/30/2015
Last Updated: 3/27/2015
Prepared & Approved by: X-GEN Pharmaceuticals, Inc., Safety Committee

The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.