ACETAZOLAMIDE EXTENDED RELEASE CAPSULE 500mg

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Date of Issue: 10/31/2017 Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: ACETAZOLAMIDE EXTENDED RELEASE CAPSULE 500mg

1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutical

1.3. Name, Address, and Telephone of the Responsible Party

Company

Accord Healthcare, Inc.
1009 Slater Road
Suite 210-B
Durham, NC 27703
USA
Telephone: 1-919-941-7880
Fax- 1-919-941-7881
www.accord-healthcare.com

1.4. Emergency Telephone Number

Emergency Number : 1-800-424-9300
Call CHEMTREC Day or Night

SECTION 2: HAZARDS IDENTIFICATION

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, it is exempt from labeling, as defined in the 29 CFR 1910.1200(b)(5)(iii).

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) It is in solid, final form for direct administration to the patient. Therefore, it is exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii).

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service.

First-aid Measures After Skin Contact: Remove contaminated clothing. If exposed or concerned: Get medical advice/attention. Immediately drench affected area with water for at least 15 minutes.

First-aid Measures After Eye Contact: Immediately rinse with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Causes skin irritation. Causes serious eye irritation. Suspected of damaging fertility or the unborn child.

Symptoms/Injuries After Inhalation: Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO_2), alcohol-resistant foam, or dry chemical. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: In powdered form: Combustible Dust.

Explosion Hazard: Dust explosion hazard in air.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO_2). Nitrogen oxides. Sulfur oxides.

Other Information: Risk of dust explosion.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Do not breathe dust. Avoid all contact with skin, eyes, or clothing. Avoid generating dust. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing. Do NOT breathe (dust). Avoid creating or spreading dust. Keep away from heat, sparks, open flames, hot surfaces. – No smoking.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Cellulose (9004-34-6)		
USA ACGIH	ACGIH TWA (mg/m³)	10 mg/m³
USA NIOSH	NIOSH REL (TWA) (mg/m³)	10 mg/m³ (total dust)

		5 mg/m³ (respirable dust)
USA OSHA	OSHA PEL (TWA) (mg/m³)	15 mg/m³ (total dust) 5 mg/m³ (respirable fraction)

Talc (Mg3H2(SiO3)4) (14807-96-6)		
USA ACGIH	ACGIH TWA (mg/m³)	2 mg/m³ (particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter)
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen containing no asbestos fibers
USA NIOSH	NIOSH REL (TWA) (mg/m³)	2 mg/m³ (containing no Asbestos and <1% Quartz-respirable dust)
USA IDLH	US IDLH (mg/m³)	1000 mg/m³ (containing no asbestos and <1% quartz)

Carbonic acid, magnesium salt (1:1) (546-93-0)		
USA NIOSH	NIOSH REL (TWA) (mg/m³)	10 mg/m³ (total dust) 5 mg/m³ (respirable dust)

Quartz (14808-60-7)		
USA ACGIH	ACGIH TWA (mg/m³)	0.025 mg/m³ (respirable particulate matter)
USA ACGIH	ACGIH chemical category	A2 - Suspected Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m³)	0.05 mg/m³ (respirable dust)
USA IDLH	US IDLH (mg/m³)	50 mg/m³ (respirable dust)
USA OSHA	OSHA PEL (TWA) (mg/m³)	50 µg/m³

8.2. Exposure Controls

Appropriate Engineering Controls : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Ensure all national/local regulations are observed.

Personal Protective Equipment : Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing : Chemically resistant materials and fabrics.

Hand Protection : Wear protective gloves.

Eye and Face Protection : Chemical safety goggles.

Skin and Body Protection : Wear suitable protective clothing.

Respiratory Protection : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Solid

Appearance : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Evaporation Rate : No data available

Melting Point : No data available

Freezing Point : No data available

Boiling Point	:	No data available
Flash Point	:	No data available
Auto-ignition Temperature	:	No data available
Decomposition Temperature	:	No data available
Flammability (solid, gas)	:	No data available
Vapor Pressure	:	No data available
Relative Vapor Density at 20°C	:	No data available
Relative Density	:	No data available
Solubility	:	No data available
Partition Coefficient: N-Octanol/Water	:	No data available
Viscosity	:	No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).

10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products: None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Cellulose (9004-34-6)	
LD50 Oral Rat	> 5000 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 5800 mg/m³ (Exposure time: 4 h)

Sodium lauryl sulfate (151-21-3)	
LD50 Oral Rat	1288 mg/kg
LD50 Dermal Rat	> 2000 mg/kg
LC50 Inhalation Rat	> 3900 mg/m³ (Exposure time: 1 h)

Poly(oxy-1,2-ethanediyl), .alpha.-(isononylphenyl)-.omega.-hydroxy- (37205-87-1)	
LD50 Oral Rat	2590 mg/kg
LD50 Dermal Rabbit	2830 mg/kg

Quartz (14808-60-7)	
LD50 Oral Rat	> 5000 mg/kg
LD50 Dermal Rat	> 5000 mg/kg

Skin Corrosion/Irritation: Causes skin irritation.

Serious Eye Damage/Irritation: Causes serious eye irritation.

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Talc (Mg3H2(SiO3)4) (14807-96-6)	
IARC group	3
National Toxicology Program (NTP) Status	Evidence of Carcinogenicity.

Quartz (14808-60-7)	
IARC group	1
National Toxicology Program (NTP) Status	Known Human Carcinogens.
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: Suspected of damaging fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects.

Chronic Symptoms: Suspected of damaging fertility or the unborn child.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Sodium lauryl sulfate (151-21-3)	
LC50 Fish 1	8 (8 - 12.5) mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	1.8 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	15 (15 - 18.9) mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
NOEC Chronic Crustacea	0.88 mg/l

Talc (Mg3H2(SiO3)4) (14807-96-6)	
LC50 Fish 1	> 100 g/l (Exposure time: 96 h - Species: Brachydanio rerio [semi-static])

12.2. Persistence and Degradability

ACETAZOLAMIDE EXTENDED RELEASE CAPSULE 500mg	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

ACETAZOLAMIDE EXTENDED RELEASE CAPSULE 500mg	
Bioaccumulative Potential	Not established.

Sodium lauryl sulfate (151-21-3)	
BCF Fish 1	(will not bioconcentrate)
Log Pow	1.6

Talc (Mg3H2(SiO3)4) (14807-96-6)	
BCF Fish 1	(no known bioaccumulation)

Dolomite (CaMg(CO3)2) (16389-88-1)	
BCF Fish 1	(no known bioaccumulation)

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

ACETAZOLAMIDE EXTENDED RELEASE CAPSULE 500mg	
SARA Section 311/312 Hazard Classes	Delayed (chronic) health hazard Immediate (acute) health hazard Fire hazard Sudden release of pressure hazard

Acetamide, N-[5-(aminosulfonyl)-1,3,4-thiadiazol-2-yl]- (59-66-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Cellulose (9004-34-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Inventory Update Reporting Rule, i.e, Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C)).

Sodium lauryl sulfate (151-21-3)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Poly(oxy-1,2-ethanediyl), .alpha.-(isononylphenyl)-.omega.-hydroxy- (37205-87-1)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	SP - SP - indicates a substance that is identified in a proposed Significant New Uses Rule.

Talc (Mg3H2(SiO3)4) (14807-96-6)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Dolomite (CaMg(CO3)2) (16389-88-1)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Carbonic acid, magnesium salt (1:1) (546-93-0)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

Quartz (14808-60-7)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State Regulations

Acetamide, N-[5-(aminosulfonyl)-1,3,4-thiadiazol-2-yl]- (59-66-5)	
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.

Cellulose (9004-34-6)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Talc (Mg3H2(SiO3)4) (14807-96-6)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Carbonic acid, magnesium salt (1:1) (546-93-0)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List

Quartz (14808-60-7)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 10/31/2017

Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Carc. 1A	Carcinogenicity Category 1A
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2

Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Sol. 2	Flammable solids Category 2
Repr. 2	Reproductive toxicity Category 2
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H228	Flammable solid
H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H350	May cause cancer
H361	Suspected of damaging fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure
H401	Toxic to aquatic life
H411	Toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)