SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition UNITED NATIONS New York and Geneva, 2019

Acetazolamide Tablet (125 mg/250 mg)

1. IDENTIFICATION

GHS Product identifier: Acetazolamide Tablets
Product code: #
Chemical Description:N-(5-Sulfamoyl-1,3,4-thiadiazol-2-yl)acetamide
Other means of identification:
Recommended use of the chemical: Diuretic, antiglaucoma, and anticonvulsant
Restrictions on use: The product should be used only for the above mentioned uses and may not be used for any other purpose than stated above.

Manufactured by:
Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification
Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route	Labels (as per, UN-GHS)	Signal Word	Warning
Skin	2	Dermal		**Hazard Statements:**	H315: Causes skin irritation H319: Causes serious eye irritation H361: Suspected of damaging fertility or the unborn child . H335: May cause respiratory irritation H363: May cause harm to breast fed children
Eye	2	-			
Reproductive toxicity	2	-			

Signal Word	**Warning**
Precautionary Statements:	P280: Wear protective gloves, protective clothing, eye and face protection. P305 + P351 + P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P332+P313: If skin irritation occurs: Get medical advice/attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362: Take off contaminated clothing. P405: Store locked up.
Other hazards	When heated to decomposition this compound emits highly toxic fumes of NOx and SOx.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Alosetron HCl

Hazardous ingredients	CAS	Content
Acetazolamide	59-66-5	49.02 %

4. FIRST-AID MEASURES

Inhalation

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Skin contact

Wash off with soap and plenty of water. Consult a physician.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion

If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and immediately call a hospital or poison control center. If the victim is convulsing or unconscious, do not give anything by mouth. Ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Fire/explosion hazard

No data available. Acetazolamide compound is probably combustible.

Specific hazards arising from the chemical

Formation of toxic gases is possible.

Toxic gases are formed by mixing materials of this class with acids, aldehydes, amides, carbamates, cyanides, inorganic fluorides, halogenated organics, isocyanates, ketones, metals, nitrides, peroxides, phenols, epoxides, acyl halides, and strong oxidizing or reducing agents. Flammable gases are formed by mixing materials in this group with alkali metals. Explosive combination can occur with strong oxidizing agents, metal salts, peroxides, and sulfides.

Personal protection

Self-contained breathing apparatus. Fire-fighters must wear self-contained breathing apparatus for firefighting if necessary.

Special exposure hazards

Do not release chemically contaminated water into drains, soil or surface water. Dispose contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Prevent contamination of soil, drains and surface waters.

Spillage procedure

Take up mechanically and collect in suitable container (adequately labelled) for disposal.

7. HANDLING AND STORAGE

Handling

Occupational hygiene

Avoid ingestion, inhalation, skin and eye contact. Avoid prolonged or repeated exposure. Handle in accordance with good industrial hygiene practice and any legal requirements.

Conditions for safe storage

Avoid dust formation and ignition sources. Ensure good local exhaust ventilation.
Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Storage facilities
Store in a cool, dry area with adequate ventilation. Keep tightly closed. Store at 25 °C

Segregation
Store locked up.
Storage conditions
Keep containers closed.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values
Components with occupational exposure limits

CAS No	Name	TWA	STEL	Source
59-66-5	N-(5-Sulfamoyl-1,3,4-thiadiazol-2-yl)acetamide	Not known	--	-
557-04-0	Magnesium Stearate	10 mg/m3		

Occupational exposure controls
Appropriate engineering controls
Maintain air concentrations below occupational exposure standards. Prevent dust formation.
General Personal Protection
Goggles, gloves, protective clothing.
Respiratory protection
Provide proper respiratory protection. Whenever possible, Self-Contained Breathing Apparatus (SCBA) should be used; if not available, use a level of protection greater than or equal to that advised under Protective Clothing.

Hand protection
Protective gloves.
Eye protection
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin and body protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: solid
Form: Tablets
Colour: White (For both 125 mg and 250 mg strengths)
Odour: N.A.

pH: 4-6 for acetazolamide suspension in water
Melting point: Not available for formulation (372 °C for acetazolamide 100%)
Boiling point: Not applicable
Flash point: Not applicable
Flammability (solid): Lower limit 40 ± 3.9g/m^3
Vapour pressure: Not applicable
Auto-ignition temperature: Not tested
Decomposition temperature: Not tested
Density: Not tested
Solubility in water: Insoluble ((980 mg/L (at 30 °C) for acetazolamide compound)
Solubility in solvents: Slightly soluble in alcohol, soluble in dilute sodium hydroxide solution

n-Octanol/Water Partition Coefficient: Not available for formulation (0.16, for acetazolamide 100%)
Viscosity: Not applicable
Oxidizing properties: Not tested
Explosivity: Stable under ordinary conditions.

Further Dust explosion Information on acetazolamide 100%
Explosive index: 121± 15 m bar/s
pKa: 7.2 i 9.0
Maximum explosion pressure: 9.4±0.5 bar
Maximum speed of escalation of pressure: 447±54 bar/s
Maximum dust/air mixture ignition energy :49.6< *MIE* < 72.3 mJ
Dust explosion class: St 1

10. STABILITY AND REACTIVITY

Conditions to avoid
Avoid moisture
Materials to avoid
Acid, Acid chlorides, acid anhydrides, oxidizing agents
Hazardous decomposition products
None under normal storage conditions. When heated to decomposition this compound emits highly toxic fumes of NOx and SOx.

11. TOXICOLOGICAL INFORMATION

Acute toxicity
Acetazolamide active ingredient has been tested for acute toxicity.

Acute toxicity:
Oral LD_{50} - >15000 mg/kg (rat)
Oral LD_{50} - 4300 mg/kg (mouse)
LD_{50} (Intraperitoneal) - 2750 mg/kg (rat)
LD_{50} (Intravenous) - 3000 mg/kg (mouse)

Sodium starch glycolate - Oral LD_{50} - 7110 mg/kg (rat)

Based on toxicity data of Acetazolamide and its excipients, Acetazolamide tabletcannot be classified for oral toxicity.

Primary Irritation

Acetazolamide

Eyes: Irritating to eyes
Eye Irritation: Active ingredient classified in category 2., sodium starch glycolate is category 2, magnesium stearate is category 2.

GHS Classification for this mixture is Eye category 2.

Skin sensitization

- Irritant to skin and mucous membranes
- Active ingredient acetazolamide, magnesium stearateand sodium starch glycolate are classified as Category 2. Hence Acetazolamide tablets are classified as category 2.

CMR consideration:

Germ cell mutagenicity:

- Data not available

GHS Classification is not possible.

Carcinogenicity

Not classifiable as human carcinogen.

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

GHS Classification for active ingredient is not possible due to lack of data.

Reproductive toxicity

- For active ingredient acetazolamide it is category 2
- Acetazolamide tablet would also be classified as category 2 based on the GHS cut-off limits.

Specific target organ toxicity single exposure:

Acetazolamide - Single exposure - Category 3

Acetazolamide Tablet is classified as category 3.

Specific target organ toxicity repeated exposure:

- No oral repeat dose studies or human evidence are available and therefore no classification is proposed.

Aspiration hazard:

GHS Classification is not possible.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Acetzolamide shows low toxicity to Daphnia and algae (EC_{50} or LC_{50} values >100 mg/L).
GHS Classification is not possible.

Persistence and degradability

Data not available.

Behavior in treatment plants

Data not available.

Additional information

Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal

Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2019 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2009

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes

Prepared on 07/10/20; Rev 0