

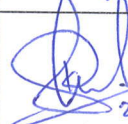
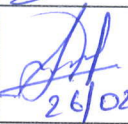
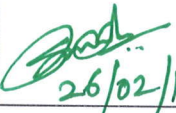


CERTIFICATE FOR SAFETY DATA SHEET
Name of the Product: Acetazolamide Tablets USP 125mg and 250mg

Product Code: 2005230 & 2005319

SDS Number: SDS/FD-001-00

Activity	Department	Name	Sign & Date
Prepared By (FD)	Formulation Development	MANOJ KULKARNI	 26/02/19
Reviewed By (FD)	Formulation development	Mohammed Hussain	 26/02/19
Reviewed By (RA)	RA	Karnet Chawla	 26/02/2019
Approved By (FD)	FD	Sudarshan Nimbalkar	 26/02/19
Authorized By (TSGQA/DQA)	DQA	S. GOPINATH	 26/02/19

Safety Data Sheet		
Company Name:	Strides Pharma Science Ltd	SDS Number: SDS/FD-001-00
Section 1: Identification		
Product Identifier		
Product name:	Acetazolamide Tablets USP 125 mg and 250mg	
Trade name:	Not applicable	
Product Code No.:	2005230 & 2005319	
Relevant identified use of the substance or mixture and use advised against		
Recommended Use:	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.	
Restrictions on Use:	Use only as directed	
Details of the supplier of the safety data sheet:		
Manufacturer name:	Strides Pharma Science Limited	
Address:	Strides Pharma Science Limited UNIT II, R. S. No.32, 33 & 34, PIMS Road, Periyakalpet, Puducherry-605014, India.	
Telephone Number-General:	+914132650900 +914132655697 +914132655698 +914132655951 +914132655952	
Emergency Telephone Number:	91 8067 840307/309	
Note: <i>This safety data sheet is written to provide safety, health and environmental information for people handling the formulated product in the work place. It is not intended to provide information relevant to consumer use of the product (PIL will be applicable for consumer).</i>		
Section 2: Hazard Identification:		
Hazard Classification of chemical mixture	Physical	Health
	Not Hazardous	Causes eye irritation Respiratory irritation Skin irritation
Signal word	WARNING	
Hazard Statement	Causes eye irritation. May be harmful if absorbed through skin. Causes skin irritation. May be harmful if swallowed. May be harmful if inhaled. Causes respiratory tract irritation.	
Label elements		

Precautionary statements	Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.		
Storage/Disposal	Dispose in accordance with local and national regulations.		
EU classification	Not available		
US GHS classification	Not available		
Section 3: Composition/Information on Ingredients			
Mixtures:			
Composition			
Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Acetazolamide	59-66-5	*	Not available
Lactose Monohydrate	64044-51-5	*	Not available
Sodium Starch Glycolate	9063-38-1	*	Not available
Maize starch (corn starch)	9005-25-8	*	Not available
Gelatin powder (250 Bloom)	9000-70-8	*	Not available
Glycerin	56-81-5	*	Not available
Purified water	7732-18-5	*	Not available
Talc	14807-96-6	*	Not available
Magnesium Stearate	557-04-0	*	Not available
*Percentage composition is not captured due to trade secret.			
Section 4: First aid measures			
General advice:	Not applicable		
Inhalation:	If breathed in, move person into fresh air. If not breathing give artificial respiration. Consult a physician.		
Skin contact:	Causes skin irritation. In case of skin contact, wash off with soap and plenty of water. Consult a physician.		
Eye contact:	In case of eye contact, rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.		
Ingestion:	If swallowed, never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.		
Most important symptoms and effects both acute and delayed:			
Symptoms:	Not Available		
Other hazards	Not available		
Indication of immediate medical attention and special treatment needed			
Notes for the doctor	Immediate medical attention is recommended for overdose.		
Special treatment	Not available		
Other information	Not available		
Section 5: Fire Fighting Measures			
Extinguishing media			

Suitable Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.		
Unsuitable Extinguishing Media	Not available		
Firefighting Procedures	Wear self-contained breathing apparatus for firefighting if necessary.		
Unusual Fire and Explosion Hazards	Not applicable		
Hazardous combustion products:	None known		
Additional Information	Not available		
Section 6: Accidental Release Measures			
Personal precautions, protective equipment and emergency procedures			
Personal Precautions:	Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.		
Emergency Procedure	Not available		
Methods and material for containment and cleaning up			
Containment/Cleanup measures	Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for disposal.		
Prohibited materials	Not available		
Section 7: Handling and Storage			
Precautions for safe handling			
Patients/ Consumers:	Not available		
Safe handling:	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.		
Fire Prevention	Not available		
Dust generation Preventions	Avoid the generation of dust.		
Environmental precautions	Do not let product enter drains.		
Conditions for safe storage, including any incompatibilities			
Technical measures and Storage Conditions:	Keep container tightly closed in a dry and well-ventilated place. Light sensitive.		
Special Packaging Materials	Not available		
Section 8: Exposure Controls and personal protection			
Exposure Limits/Guidelines			
Component Name	Result	OSHA	Other agency Information
Acetazolamide	TWAs/ STELs	No data available	No data available
Lactose Monohydrate	TWAs/ STELs	No data available	No data available

Sodium Starch Glycolate	TWAs/ STELs	No data available	No data available
Corn starch	TWA ACGIH TLV/ TWA OSHA PEL	10 mg/m ³ 5 mg/m ³ (respirable) 15 mg/m ³ (total dust)	No data available
Gelatin powder (250 Bloom)	TWAs/ STELs	No data available	No data available
Glycerin	TWAs/ STELs	No data available	No data available
Purified water	TWAs/ STELs	No data available	No data available
Talc	PEL/TWA	20 mppcf	2 mg/m ³
Magnesium Stearate	TWA/PEL	5 mg/m ³ (Respirable fraction for nuisance dusts) 15 mg/m ³ Total dust	10 mg/m ³
Note: The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.			
Exposure Controls			
Engineering Controls	Contains no substances with occupational exposure limit values.		
Personal protective equipment			
Hands:	Not available		
Eyes:	Chemical safety goggles recommended for handling damaged tablets or tablets.		
Skin:	Handle with gloves.		
Respiratory protection:	(EN 143) respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).		
Special requirements for PPE:	Not available		
Section 9: Physical and Chemical properties			
Information on physical and chemical Properties			
Material Description:			
Physical Form:	Solid, Tablet		
Color:	White to off white		
Odour:	Not available		
General Properties:			
Boiling point	Not available		
Melting point:	Not available		
Water solubility:	Not available		
Solvent solubility:	Not available.		
Specific gravity / Relative density:	Not available.		
pH	Not available.		
Decomposition temperature:	Not available.		
Viscosity	Not available.		

Density:	Not available.				
Partition coefficient:	Not available.				
Volatility and Flammability	Not available.				
Vapor pressure:	Not available.				
Vapor density	Not available.				
Evaporation rate:	Not available.				
Flash Point	Not available.				
Upper Exposure limit:	Not available.				
Lower Exposure limit:	Not available.				
Flammability (solid, gas):	Not available.				
Section 10: Stability and Reactivity					
Reactivity	Not available				
Chemical stability under normal ambient Temperature	Stable under recommended storage conditions.				
Possibility of hazardous reactions	None known				
Conditions to avoid	Not available				
Incompatible materials	Avoid oxidizing agents.				
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions – Carbon oxides, nitrogen oxides (NO _x), sulfur oxides.				
Section 11: Toxicological information					
Information on toxicological effects					
General Information: The information included in this section describes the potential hazards of the individual ingredients.					
Components					
Components	CAS No	Acute toxicity			
		Species	Route	End Point	Dose
Acetazolamide	59-66-5	Mouse	Oral	LD 50	4300 mg/kg
Lactose Monohydrate	64044-51-5	No Data Available			
Sodium Starch Glycolate	9063-38-1	Rat	Oral	LD50	>5000mg/kg
Corn starch	9005-25-8	Mouse	Intraperitoneal	LD50	6600 mg/kg
Gelatin powder (250 Bloom)	9000-70-8	No Data Available			
Glycerin	56-81-5	No Data Available			
Purified water	7732-18-5	No Data Available			
Talc	14807-96-6	Rat	Oral	LD50	1600 mg/kg
Magnesium Stearate	557-04-0	Rat	Oral	LD 50	>2000mg/kg
		Rat	Inhalation	LC 50	>2000mg/m ³

Potential health effects		
Inhalation:	If breathed in, move person into fresh air. If not breathing give artificial respiration. Consult a physician.	
Ingestion:	If swallowed, never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.	
Eye contact:	In case of eye contact, rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.	
Skin contact:	Causes skin irritation. In case of skin contact, wash off with soap and plenty of water. Consult a physician.	
Section 12: Ecological Information		
Toxicity		
Persistence and degradability	No data is available.	
Bio accumulative potential	No data is available.	
Mobility in Soil	No data is available.	
Other adverse effects	None known	
Section 13: Disposal Considerations		
Product waste	Observe all federal, state, and local environmental regulations. Contact a licensed professional waste disposal service to dispose of this material.	
Packaging waste	Not available	
Section 14: Transport information		
UN Number	Not available	
UN shipper name	Not available	
Transport hazard class:	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, US or European ground transport purposes.	
Environmental hazards	Not available	
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable	
Section 15: Regulatory Information		
Safety, health and environmental regulations/legislation specific for the substance or mixture		
Component Name	CAS number	CERCLA/SARA Emission Reporting
Acetazolamide	59-66-5	Not Listed
Lactose Monohydrate	64044-51-5	Not Listed
Sodium Starch Glycolate	9063-38-1	Not Listed
Corn starch	9005-25-8	Not Listed



Gelatin powder (250 Bloom)	9000-70-8	Not Listed
Glycerin	56-81-5	Not Listed
Purified water	7732-18-5	Not Listed
Talc	14807-96-6	Not Listed
Magnesium Stearate	557-04-0	Not Listed
Section 16: Other information		
Reason for revision: (Include Change control number)	New Safety Data Sheet prepared	
Revision date:	26/02/2019	
Version Number:	00	