

SAFETY DATA SHEETS

This SDS packet was issued with item:

078940892

N/A

Safety data Sheet

Company Name: Strides Shasun Limited

Section 1: Identification

Product Identifier

Product name: Amantadine hydrochloride Tablets USP 100mg

Trade name: Not Applicable

Product Code No.: 3007948/3007949

Relevant identified use of the substance or mixture and use advised against

Recommended Use: Finished pharmaceutical product as an antiviral

Restrictions on Use: Acute toxicity may be attributable to the anticholinergic effects of amantadine. Drug overdose has resulted in cardiac, respiratory, renal or central nervous system toxicity. Cardiac dysfunction includes arrhythmia, tachycardia and hypertension.

Amantadine can exacerbate mental problems in patients with a history of psychiatric disorders or substance abuse.

Amantadine Hydrochloride Tablets, USP has anti cholinergic effects and may cause mydriasis, it should not be given to patients with untreated angle closure glaucoma.

Amantadine should not be discontinued abruptly in patients with Parkinson's disease since a few patients have experienced a parkinsonian crisis, i.e., a sudden marked clinical deterioration, when this medication was suddenly stopped. The dose of anticholinergic drugs or of amantadine should be reduced if atropine-like effects appear when these drugs are used concurrently. Abrupt discontinuation may also precipitate delirium, agitation, delusions, hallucinations, paranoid reaction, stupor, anxiety, depression and slurred speech.

Details of the supplier of the safety data sheet: Strides Shasun Limited

Manufacturer name: Strides Shasun Limited

Address: Strides Shasun Ltd
Formulation Division
RS No: 32 -34, PIMS Road
Periyakalpet
Puducherry-605 014, India

Telephone Number- General: 91 0413 2655946

Emergency Telephone Number: : 0413-2655154 / 1-800-222-1222

Note: 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).

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Section 2: Hazard Identification:

Hazard Classification of the chemical mixture: No data Available

Signal Word: No data available

Hazard Statement: Slightly hazardous in case of skin contact (irritant), of eye contact (irritant), of ingestion, of inhalation.

Label elements

Precautionary statements : Obtain special instructions before use

Storage/Disposal: Store at 25°C (77°F) excursion permitted to 15°C – 30°C(59° to 86°F) [See USP Controlled Room Temperature]. Dispense in a tight light resistant container as defined in the USP, with child resistant closure.

US GHS Classification: The product contains no substances which at their given concentration, are considered to be hazardous to health.

Section 3: Composition/Information on Ingredients

Mixtures: Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and EU EINECS.

Composition			
Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Amantadine hydrochloride	665-66-7	100 mg	Not classified
Microcrystalline cellulose 101	9004-34-6	-	Not classified
Sodium starch glycolate NF (TYPEA)	9063-38-1	-	Not classified
Colloidal silicon dioxide NF	7631-86-9	-	Not classified
Povidone K 30 BP/Ph. Eur/USP	9003-39-8	-	Not classified
FD&C Yellow #6 / Sunset Yellow FCF AL 22% / 12%	-	-	Not classified
Magnesium stearate Veg NF/Ph Eur	557-04-0	-	Not classified

Note: Percentage composition for in-actives is not captured due to trade secret.

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Section 4: First aid measures

General Information:

Inhalation: In the final form, not a likely route of exposure. However, in case of inhalation, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult administer oxygen. Seek medical attention immediately.

Contact with skin: If redness, dryness or other signs of irritation develop, wash the affected area with plenty of warm water and soap. If irritation persists, seek medical attention immediately

Contact with eyes: In case of eye contact, flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Seek medical attention immediately

Ingestion:

In case of accidental ingestion, give the victim several glasses of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Do not force an unconscious or convulsing person to drink liquids or to vomit. Seek medical attention immediately

Overdose

- Acute toxicity may be attributable to the anticholinergic effects of amantadine.
- Drug overdose has resulted in cardiac, respiratory, renal or central nervous system toxicity. Cardiac dysfunction includes arrhythmia, tachycardia and hypertension.
- Central nervous system effects that have been reported include insomnia, anxiety, agitation, aggressive behavior, hypertonia, hyperkinesia, ataxia, gait abnormality, tremor, confusion, disorientation, depersonalization, fear, delirium, hallucinations, psychotic reactions, lethargy, somnolence and coma.
- Seizures may be exacerbated in patients with prior history of seizure disorders.
- Hyperthermia has also been observed in cases where a drug overdose has occurred.

UN GHS/ EU EINECS:

Effects: Not applicable

Indication of any immediate medical attention and special treatment needed:

Notes for the doctor: Treat symptomatically.

Special treatment: No data available

Other information: No Data available

Section 5: Fire Fighting Measures

Extinguishing media

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Suitable Extinguishing Media: Use an appropriate media including water spray, dry powder, foam, carbon dioxide

Unsuitable Extinguishing Media: No data reported

Firefighting Procedures: No data available

Unusual Fire and Explosion Hazards: Slightly explosive in the presence of open flames and sparks. As with most organic solids, fire is possible at elevated temperatures.

Hazardous Combustion Products: When heated to decomposition it emits toxic gases such as carbon oxides (CO and CO₂) and nitrogen oxides (NO and NO₂). These toxic fumes may be released in a fire involving Amantadine HCl.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation.

Emergency Procedures: No data available

Methods and material for containment and cleaning up

Containment/Cleanup Measures:

Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

Prohibited Materials: not known

Section 7: Handling and Storage

Precautions for safe handling

Protective measures:

Safe Handling : Use safety goggles, gloves and respirators.

Fire prevention : no data available

Dust generation preventions : No data available

Environmental precautions : Do not discharge into drains/surface waters/groundwater

Storage : Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight light resistant container as defined in USP.

Incompatibilities : No Data Available

Technical measures and storage conditions: Requirements for storage rooms and vessels: Store in original container. When using, do not eat, drink or smoke. Should be handled in closed systems, if

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possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.

Special Packaging Materials: No data available

Requirement for storage rooms and assembly: No data available

Incompatible Materials or Ignition Sources: No data Available

Section 8: Exposure Controls and personal protection

Control Parameters:

Exposure Limits/ Guidelines: Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits			
Component Name	Result	OSHA	Other agency information
Amantadine hydrochloride	TWAs/STELs	No data	No data
Microcrystalline cellulose 101	PEL/TWA	OSHA PEL: TWA 15 mg/m ³ (total) TWA 5 mg/m ³ (resp)	NIOSH REL: TWA 10 mg/m ³ (total) TWA 5 mg/m ³ (resp)
Sodium starch glycolate NF (TYPEA)	PEL/TWA	No data	No data
Colloidal silicon dioxide NF	PEL/TWA	80 mg/m ³ (PEL)	6 mg/m ³ (REL-TWA) NIOSH
Povidone K 30 BP/Ph.	-	No data	No data
FD&C Yellow #6 / Sunset Yellow FCF AL 38% - 42%	PEL/TWA	No data	No data
Magnesium stearate Veg NF/Ph.Eur	TWA	No data	TLV: (as stearate) 10 mg/m ³ as TWA A4 (ACGIH 2001)

Exposure Controls

Engineering Controls: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protective Equipment:

In a manufacturing setting, the following personal protective equipment requirements apply:

Hands: Chemical resistant protective gloves (EN 374)

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Eyes: If contact is likely, safety glasses with side shields are recommended.

Skin: For prolonged or repeated skin contact use suitable protective gloves.

Respiratory protection: Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.

Special requirements for PPE: Handle in accordance with good industrial hygiene and safety practice. Do not breathe dust. Avoid contact with skin, eyes and clothing.

Section 9: Physical and Chemical properties

Information on physical and chemical Properties

Material Description:

Physical form	Solid
Color	Peach
Odor	Odorless
Description	Peach colored, round shaped, flat, beveled edge tablet, debossed as "S" on one side and "502" on other side

General Properties:

Boiling Point	Not Available	Melting Point	360°C
Water Solubility	Freely Soluble in water; soluble in alcohol and in chloroform.	Solvent solubility	Water: 6290mg/L
Specific Gravity/Relative	Not available	pH	3.0-5.5
Decomposition Temperature	Not available	Viscosity	Not available
Density	Not Available	Partition co-efficient	2.44

Volatility and Flammability:

Vapor Pressure	Not Applicable	Vapor Density	Not applicable
Evaporation Rate	Not Applicable	UEL (Upper exposure Limit)	Not Applicable
Flash Point	Not Available	LEL (Lower Exposure Limit)	Not Applicable
Flammability (Solid, Gas)	Not Available		

Section 10: Stability and Reactivity

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Reactivity: No decomposition when stored and applied as directed.

Chemical Stability under normal ambient temperature: The product is stable and non-reactive under normal conditions of use, storage and transport.

Possibility of Hazardous Reactions: No dangerous reaction known under conditions of normal use.

Any stabilizer requirement on storage: No data available

Conditions to Avoid: Contact with incompatible materials

Incompatible materials: No data Available

Hazardous decomposition products: None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

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
Amantadine hydrochloride	665-66-7	700 mg/kg (Mus) 800 mg/kg (rat)
Microcrystalline cellulose 101	9004-34-6	> 5,000 mg/kg (rat)
Sodium starch glycolate NF (TYPEA)	9063-38-1	-
Colloidal silicon dioxide NF	7631-86-9	>5000 mg/kg (Rat)
Povidone K 30 BP/Ph. Eur/USP	9003-39-8	8000 mg/kg (Rat) 8100 mg/kg (Mouse)
FD&C Yellow #6 / Sunset Yellow FCF AL 38% - 42%	-	-
Magnesium stearate Veg NF/Ph.Eur	557-04-0	Oral LD50 > 2000 mg/kg

Potential Health Effects

Inhalation

Acute (Immediate): Dust may cause respiratory tract irritation

Chronic (Delayed): No data available

Skin

Acute (Immediate): May cause skin irritation and Mucous membranes.

Chronic (Delayed): No data available

Eye

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Acute (Immediate): Dust may cause eye irritation

Chronic (Delayed): No data available

Ingestion

Acute (Immediate): No data available

Chronic (Delayed): No data available

Section 12: Ecological Information

Toxicity: No data Available

Persistence and degradability: No data Available

Bio accumulative potential: No data Available

Mobility in Soil: No data Available

Other adverse effects: No data Available

Section 13: Disposal Considerations

Product Waste: Dispose the waste in accordance with all applicable Federal, State and local laws.

Packaging Waste: No data available

Section 14: Transport information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

UN Number	(Four digit number)
UN Shipper Name	No data Available
Transport Hazard Class	No data Available
Environmental Hazards	No data Available
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No data Available

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Section 15: Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

Component	CAS No.:	CERCLA/SARA Emission Reporting
Amantadine hydrochloride	665-66-7	Not listed
Microcrystalline cellulose 101	9004-34-6	Not listed
Sodium starch glycolate NF (TYPEA)	9063-38-1	Not listed
Colloidal silicon dioxide NF	7631-86-9	Not listed
Povidone K 30 BP/Ph. Eur/USP	9003-39-8	Not listed
FD&C Yellow #6 / Sunset Yellow FCF AL 38% - 42%	-	Not listed
Magnesium stearate Veg NF/Ph.Eur	557-04-0	Not listed

Note: Superfund Amendments and Reauthorization Act

Or Superfund or Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA)

Section 16: Other information

MSDS was revised into new SDS format as per the Guidance of OSHA and GHS.

Date of Preparation : 27/04/2017

Revision No : 00

Reason for Revision : Not Applicable

Revision Date : Not Applicable