

**MATERIAL SAFETY DATA SHEET****Section I - PRODUCT IDENTIFICATION**

Product Name: Amifostine for Injection , USP (500mg/ vial)
Company Name: Sun Pharmaceutical Industries Ltd
Acme Plaza, Andheri-Kurla Road, Andheri (E)
Mumbai – 400 059, INDIA

Section II - COMPOSITION AND INGREDIENTS

Chemical Name	Composition (per vial)
Amifostine (anhydrous basis)	500 mg

Amifostine for Injection is a sterile parenteral drug presented as a powder . It must be reconstituted with 0.9% Sodium chloride Solution prior to administration.

Section III - HEALTH HAZARD DATA

Routes of Entry: Primary occupational exposure routes are via inhalation, absorption, or ingestion.

Health Hazard (Acute & Chronic): Amifostine is a drug used to reduce the risk of kidney problems caused by the use of Cisplatin or to reduce dry mouth caused by radiation treatment. It may affect the gastrointestinal and central nervous system and may cause headache and dizziness upon exposure. Also may cause nausea, vomiting, and irritation to eyes, skin and respiratory tract. Chronic affects may cause changes in blood composition and lower blood pressure.

Carcinogenicity:

NTP: NO IARC Monographs: NONE OSHA Regulated: NO

Signs & Symptoms of Exposure: Immediate side effects may include nausea and/or vomiting or a transient reduction in blood pressure, which has on rare occasions resulted in a short term loss of consciousness (fainting). Other side effects may include flushing/feeling of warmth, chills/feeling of cold, dizziness, somnolence, hiccups, and/or sneezing. In rare cases, allergic reactions (mild skin rashes to rigors) or clinically relevant hypocalcaemia may occur

Medical Conditions Generally Aggravated by Exposure: Persons with known hypersensitivity to aminothiol compounds.

BVL Hazard Category: 2



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Section IV - FIRST AID MEASURES

Eye Exposure: Wash eyes with large amounts of water or normal saline for 15 minutes. Observe for signs of irritation. If irritation is present, seek medical attention.

Skin Exposure: Remove contaminated clothing. Wash affected area with soap or mild detergent and water for 15 minutes. Observe for signs of irritation. If irritation is present, seek medical attention.

Ingestion: If ingestion occurs, induce vomiting immediately and seek medical attention from a physician immediately. Never induce vomiting on an unconscious person.

Inhalation: If difficulty breathing, administer oxygen. Seek medical attention immediately. Overdose in humans is unlikely to occur. The most likely symptom of over dosage is hypotension, which should be managed by infusion of normal saline and other supportive measures, as clinically indicated.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point : Not applicable

LEL : Not Applicable

UEL : Not Applicable

Flammable Limits : Not applicable

Extinguishing Media : Use CO₂, dry chemicals, foam, water.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus to avoid inhalation of smoke and protective clothing. Product is not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to land: Wet Amifostine with water and absorb with absorbent materials and dispose of according to local, state, and federal regulations.

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

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



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Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above.

Wear latex or nitrile gloves, safety glasses (protective coveralls and shoe covers for large spills) and a disposable dust/mist respiratory (N95). Avoid generating power/dust.

Place spillage in appropriate container labeled for waste disposal.

Waste Disposal Method: Incineration in an approved/permitted incinerator is recommended.

Refer to local, state, and federal rules.

Precautions to be taken in handling and storing: Store lyophilized vials at Controlled Room Temperature 20°-25°C (68°-77°F)

Other Precautions: None

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

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

Ventilation: Handle product in a well-ventilated area.

Protective Gloves: Nitrile or latex

Eye Protection: Safety glasses

Other Protective Clothing or Equipment: Lab Coat

Work/Hygienic Practices: Wash hands following use; no eating, drinking, or smoking while handling product.



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Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid (Powder)

Specific Gravity: Not applicable

Appearance and Odor: White powder. Forms a clear, colorless solution when reconstituted in 0.9% Sodium Chloride Injection, USP

Melting Point: Not available

Boiling Point: Not applicable

Evaporation Rate: Not applicable

Vapor Pressure: Not applicable

Solubility in Water: 450,000 mg/L

Vapor Density: Not applicable

pH: 6.5-7.5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable under normal conditions

Incompatibility (Materials to Avoid): Strong oxidizing agents

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

Hazardous Polymerization: Not known to occur

Conditions to Avoid: Store away from acids and oxidizers



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Section XI - TOXICOLOGICAL INFORMATION

For Amifostine: RTECS # TE6491000

LD₅₀ rat, intraperitoneal = 418 mg/kg
LD₅₀ mouse, intravenous = 557 mg/kg
LD₅₀ mouse, oral = 842 mg/kg
LD₅₀ mouse, intramuscular = 514 mg/kg
TD_{LO} man, oral = 54 mg/kg
LD₅₀ mouse, intraperitoneal = 321 mg/kg
LD₅₀ monkey, oral = >10gm/kg
LD₅₀ guinea pig, oral = 635 mg/kg

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

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Amifostine. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted incinerator.
Review local, state, and federal regulations.

Section XIV - TRANSPORTATION INFORMATION

Amifostine for Injection is not a DOT Hazardous Material.
Amifostine is not a Marine Pollutant.