SAFETY DATA SHEET

Magnesium Sulphate in water for Injection

SECTION – 1: IDENTIFICATION

Name of the product	Magnesium Sulfate In Water for Injection (0.325 mEq Mg++/mL), 40 mg/mL (2 g/50 mL), 40 mg/mL (4g/100mL)
Name of the organization	Amneal Injectables Pvt. Ltd. at Survey Sr. No. 506 & 508, Village : Palli, Tal : Kadi, Dist: Mehsana, Gujarat : 382165 India
Emergency contact numbers	Phone : 91 02764350100
Synonyms for drug used in the product	No information available
Therapeutic use	Specified quality tests and assay use only

SECTION - 2: HAZARDS IDENTIFICATION

Principal Hazards of the product	Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008
Harmful Effect of the drug on Health	Not classified in accordance with international standards for workplace safety
Effects on the Environment	Should not be released into the environment.
Physical & Chemical Hazards	No data available.Formation of toxic gases is possible during heating or fire. Emits oxides of sulfur under combustion.

SECTION – 3: COMPOSITION/INFORMATION ON INGREDIENTS

Usual Chemical Name of the drug used in the Injection		Magnesium Sulphate in water for Injection	
CAS Number for the drug used in the vial/bags		10034-99-8	
Ingredient Contributing to Hazard			
Ingredients of the product	Approximate Percent by Weight Qty	Class	Risk Phrases
Magnesium Sulphate in water for Injection	(0.325 mEq Mg++/mL) 40 mg/mL (2 g/50 mL)	Not known	Not known

*** These materials are considered non-hazardous under EU, US and Canadian regulations.**

NOTE: This MSDS is written to address potential worker health and safety issues associated with the handling of the formulated final product which is a vials, e.g., during the transportation, distribution, and use by medical personnel. For worker health and safety information during the manufacture of Magnesium Sulphate in water, please refer to the MSDS on each component.

SECTION - 4: FIRST-AID MEASURES

Contact With Skin	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
Contact With Eyes	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
Inhalation	Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
Instruction for the physician	Treat according to symptoms. Keep the victim under medical surveillance.
Protection for first aiders	Use mask. Safety glasses and gloves. Wash the hand with plenty of water.

SECTION - 5: FIRE-FIGHTING MEASURES

Specific hazards	No specific fire or explosion hazard.
Fire extinguishing media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool fire-exposed containers.
Protection equipment	As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.
Other advice	Keep product and empty container away from heat and sources of ignition.

SECTION – 6: ACCIDENTAL RELEASE MEASURES

Personal precautions	Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation
Precautions for environmental Protection	Should not be released into the environment.
Cleaning methods	Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

SECTION -7: HANDLING AND STORAGE

Handling Appropriate technical measures	Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.
Storage Recommended storage conditions	Keep container tightly closed in a dry and well-ventilated place. To maintain product quality: Keep refrigerated.
Recommended packaging materials	BAGS in aluminium pouches. Aluminium pouches in corrugated boxes
Precautions	Wear suitable protective clothing

SECTION - 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Technical measures	Ensure that eyewash stations and safety showers are close to the workstation location
Respiratory protection	Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.
Hand protection	Compatible chemical-resistant gloves
Eye protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 66(EU). Safety glasses
Body and skin protection	Standard working suit
Specific safety protection	Do not drink or eat during handling.
Exposure limits	Not available

SECTION - 9: PHYSICAL AND CHEMICAL PROPERTIES

Size/shape/colour description of the bags or Appearance	Clear solution
Form	Liquid
Odor	Odorless
PH	No data Available
Water Solubility	Soluble in water
Boiling Point	No data available
Melting Point	No data available
Molecular Weight	No data available
Vapor Pressure	No data available
Specific gravity	No data available
Percent Volite	No data available
Vapor density	No data available
Evaporation	No data available
Appearance	Clear, Colorless

SECTION - 10: STABILITY AND REACTIVITY

Stability	Material is stable under normal conditions.
Conditions to avoid	No information available.
Materials to avoid	No information available.
Hazardous decomposition Products	None under normal use conditions
Incompatibility	No information available.
Hazardous Polymerization	No information available.

SECTION - 11: TOXICOLOGICAL INFORMATION

Routes of Entry:Magnesium Sulphate	Dermal contact. Eye contact. Ingestion.
Toxicity to Animals: Acute	LD50 Oral - Rat - male and female - > 2.000 mg/kg LD50 Dermal - Rat - male and female - > 2.000 mg/kg
OEL	No information available
Chronic Effects on Humans:	No information available
Other Toxic Effects on Humans:	No information available
Special Remarks on Toxicity to Animals:	No information available
Special Remarks on Chronic Effects on Humans:	No information available
Special Remarks on other Toxic Effects on Humans:	Diarrhea, Vomiting, Central nervous system depression To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION - 12: ECOLOGICAL INFORMATION

Persistence / degradation of the drug	The methods for determining the biological degradability are not applicable to inorganic substances.
Bioaccumulation	No data available
Aquatic Toxicity	No data available Environmental properties have not been investigated. Releases to the environment should be avoided.

SECTION - 13: DISPOSAL CONSIDERATIONS

Product disposal	Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification
Disposal of contaminated Packaging & Personal protective equipment	As Above

SECTION - 14: TRANSPORT INFORMATION

Land	RTMD	Class	Not dangerous goods
Rail	RID/ADR	Class	Not dangerous goods
Sea	IMCO/IMDG	Class	Not dangerous goods
Air	OACI/IATA	Class	Not dangerous goods
River	DON/AONR	Class	Not dangerous goods
UN proper shipping name DOT / IATA		Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.	

SECTION - 15: REGULATORY INFORMATION

Eec regulations	US federal regulations CERCLA/SARA Hazardous Substances - Not applicable
Federal and State Regulations:	TSCA 8(b) inventory: Not applicable
Protective Equipment:	Gloves. Lab coat. Dust respirator. Be sure to use an approved/certified respirator or equivalent. Wear appropriate respirator when ventilation is inadequate. Splash goggles.
Hazard category	Not applicable
Hazard Class	Not applicable
U.S. OSHA Classification	TSCA inventory list: The product is not applicable TSCA, It is FDA regulated

SECTION - 16: OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

EC50 = concentration that causes an effect in 50% of test organisms
LC50 = concentration that is lethal in 50% of test organisms
NOEC = No Observed Effect Concentration

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