



SAFETY DATA SHEET

Section 1: Identification	
Material	Magnesium Sulfate Injection USP, 1g/2mL, 5g/10mL, 10g/20mL, 25g/50mL (500mg/mL)
Recommended use	Pharmaceutical product used as electrolyte replacement, anticonvulsant
Manufacturer	Aspiro Pharma Limited, Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Classification of the Substance or Mixture GHS - Classification	Not classified as hazardous
Label Elements Signal Word: Hazard Statements:	Not Classified Not classified in accordance with international standards for workplace safety
Other Hazards	An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).
Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.	
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Magnesium sulfate	10034-99-8
Nitrogen	7727-37-9
Sodium Hydroxide	1310-73-2
Sulfuric acid	7664-93-9
Water for Injection	7732-18-5
Section 4: First-Aid Measures	
Eye Contact	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention



Skin Contact	Wash skin with soap and water. If skin irritation persists, call a physician
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately
Inhalation	Move to fresh air. If discomfort persists, get medical attention
Most Important Symptoms and Effects, Both Acute and Delayed	
Medical Conditions Aggravated by Exposure	None known
Indication of the Immediate Medical Attention and Special Treatment Needed	None
Notes to Physician	
Section 5: Fire-Fighting Measures	
Extinguishing Media	As for primary cause of fire
Special Hazards Arising from the Substance or Mixture	
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire. Emits oxides of sulfur under combustion
Fire / Explosion Hazards	Not applicable
Advice for Fire-Fighters	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus
Section 6: Accidental Release Measures	
Personal Precautions, Protective Equipment and Emergency Procedures	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and Material for Containment and Cleaning Up	
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.



Section 7: Handling and Storage	
Precautions for Safe Handling Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.	
Conditions for Safe Storage, Including any Incompatibilities	
Storage Conditions	Store as directed by product packaging
Incompatible Materials	None known
Specific end use(s)	No data available
Section 8: Exposure Controls/Personal Protection	
Engineering Controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.
Personal Protective Equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)



Section 9: Physical and Chemical Properties	
Physical State	Injection
Route of administration	Intravenous or Intramuscular
Description	<p>Magnesium Sulfate Injection, USP is a Clear colorless solution.</p> <p>Magnesium Sulfate Injection, USP 1g/2 mL – 25 vials Carton - 31722-394-32</p> <p>Magnesium Sulfate Injection, USP 5g/10 mL - 25 Vials Carton - 31722-394-33</p> <p>Magnesium Sulfate Injection, USP 10g/20 mL - 25 Vials Carton - 31722-394-34</p> <p>Magnesium Sulfate Injection, USP 25g/50 mL - 25 Vials Carton - 31722-394-35</p>
Section 10: Stability and Reactivity	
Reactivity	No data available
Chemical Stability	Stable under normal conditions of use.
Possibility of Hazardous Reactions Oxidizing Properties Conditions to Avoid Incompatible Materials Hazardous Decomposition Products	<p>None</p> <p>None known</p> <p>None known</p> <p>Thermal decomposition products include oxides of sulfur</p>
Section 11: Toxicological Information	
Information on Toxicological Effects General Information	The information included in this section describes the potential hazards of the active ingredient(s).
Known Clinical Effects	Adverse effects associated with therapeutic use include flushing, sweating, decrease in blood pressure (hypotension), circulatory failure, central nervous system depression
<u>Acute Toxicity: (Species, Route, End Point, Dose)</u>	
Magnesium sulfate heptahydrate	
Rat Oral LDmin. 5000 mg/kg Mouse Oral LDmin. 3000mg/kg	
<u>Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))</u>	
Magnesium sulfate heptahydrate	
Fertility and Embryonic Development Rat Oral 450 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus	



<u>Genetic Toxicity: (Study Type, Cell Type/Organism, Result)</u>	
Magnesium sulfate heptahydrate Bacterial Mutagenicity (Ames) <i>Salmonella</i> Negative	
Carcinogen Status	See below . The International Agency for Research on Cancer (IARC) and the United States National Toxicology Program (NTP) have classified occupational exposure to strong inorganic acid mists containing sulfuric acid' as a known human carcinogen. This classification applies only to sulfuric acid when generated as a mist. This classification is debated within the scientific community and there is disagreement as to whether or not a cause and effect relationship between cancer and 'occupational exposure to strong inorganic acid mists containing sulfuric acid' exists.
SULPHURIC ACID ... % IARC:	Group 1 (Carcinogenic to Humans)
Section 12: Ecological Information	
Environmental Overview	Environmental properties have not been investigated. Releases to the environment should be avoided
Toxicity	No data available
Persistence and Degradability	No data available
Bio-accumulative Potential	No data available
Mobility in Soil	No data available
Section 13: Disposal Considerations	
Waste Treatment Methods	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater
Section 14: Transport Information	
The following refers to all modes of transportation unless specified below Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations	



Section 15: Regulatory Information	
Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture	
EU EINECS/ELINCS List	231-639-5
Water for Injection	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register	Present
EU EINECS/ELINCS List	231-791-2
Magnesium sulfate heptahydrate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Section 16: Other Information	
Issue Date : 06-06-2025	
Version : 00	
Further information	
Revision date: Nil	
Revision note: Nil	
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