



## 1 IDENTIFICATION OF THE SUBSTANCE OR MIXTURE AND OF THE SUPPLIER

**Product Name:** MAGNESIUM SULFATE IN 5% DEXTROSE INJECTION

**Distributed By:** WG Critical Care, LLC.  
120 Route 17 North  
Suite 115  
Paramus, NJ 07652 USA

**Customer Service Phone Number:** 1-888-493-0861  
**Emergency Phone Number:** 1-866-562-4708 (ProPharma)

**Product Use:** Magnesium Sulfate in 5% dextrose injection, USP is indicated for the prevention and control of seizures in preeclampsia and eclampsia, respectively.

This is a pharmaceutical product designed to be prescribed by a licensed health care professional. For Recommended Used refer to information containing in the Package Insert.

**Product Type:** Prescription Drug  
**Container Information:** Plastic Container

## 2 HAZARDS IDENTIFICATION

### Classification of Substance or Mixture:

**Hazard Symbols:** N/A

**Health Hazard:** Not a hazardous substance or mixture:

Not classified as hazardous according to the Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004) 3rd Edition, Safe Work Australia. Not classified as dangerous goods according to the Australian Dangerous Goods Code (ADG).

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<b>Hazard Class:</b>	This product is not hazardous per the Globally Harmonized System of Classification and Labelling (GHS)
<b>Precautionary Statements (GHS US):</b>	<p>P102 Keep out of reach of children. -This statement applies only where the substance is available to the general public.</p> <p>P103 Read label before use. - This statement applies only where the substance is available to the general public.</p>
<b>OSHA Regulatory Status:</b>	<p>This material is not considered hazardous by the OSHA Hazard Communication Standard, OSHA 29 CFR 1910.1200</p> <p>This product is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows in this Safety Data Sheet (SDS).</p>
<b>Emergency Overview:</b>	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.
<b>Precautionary Statements Disposal:</b>	Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.
<b>Hazards Not Otherwise Classified (HNOC):</b>	None known.
<b>Unknown Acute Toxicity:</b>	Not applicable.

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>	<u>GHS Classification</u>
Magnesium Sulfate Heptahydrate	1	10034-99-8	Not Listed
Water for Injection	-	7732-18-5	Not Listed
Dextrose Monohydrate	5	14431-43-7	Not Listed
Sodium Hydroxide	*	1310-73-2	Skin Corr. 1A (H314)
Sulfuric Acid	*	7664-93-9	Skin Corr. 1A (H314)

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

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\*to adjust pH

## 4 FIRST AID MEASURES

<b>GENERAL:</b>	Consult a physician if necessary.
<b>INHALATION:</b>	Remove to fresh air and if discomfort persists, seek medical assistance.
<b>EYES:</b>	Immediately flush eye s with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eye lids with fingers. Get immediate medical attention.
<b>SKIN:</b>	Remove any contaminated clothing and wash the affected area with water, then soap and water. If rash or soreness develops, seek medical advice.
<b>INGESTION:</b>	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
<b>Recommendations for Immediate Medical Care and First Responders:</b>	No specific recommendations. Normal washroom facilities can be used.
<b>Description of the most important symptoms or effects, and any symptoms that are acute or delayed:</b>	Ingestion of magnesium sulfate has a laxative effect and can result in nausea, vomiting, abdominal pain, diarrhea and electrolyte loss. Systemically, magnesium sulfate can cause sedation, flushing, sweating, hypotension, hypothermia, reduced respiration rate, hypotonia, depressed reflexes, reduced heart rate, altered ECG and circulatory collapse. Administration to pregnant women prior to delivery can result in hypotension, hyporeflexia, hypotonia and respiratory depression in the neonate.
<b>Indication of any immediate medical attention and special treatment needed</b>	
<b>Note to physicians:</b>	See patient package insert in shipping carton for complete information.

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## 5 FIRE FIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable extinguishing media:</b>	None known.
<b>Special hazards arising from the substance or mixture:</b>	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.
<b>Advice for Fire-Fighters, Protective Equipment and Precautions:</b>	Fire fighter should wear positive pressure self-contained breathing apparatus (SCBA), flame and chemical resistant clothing, boots and gloves.
<b>Explosion Data:</b>	Not Applicable
<b>Sensitivity to Mechanical Impact:</b>	Not Applicable
<b>Sensitivity to Static Discharge:</b>	Not Applicable

## 6 ACCIDENTAL RELEASE MEASURE

<b>Personal precautions, protective equipment and emergency procedures</b>	<p>Evacuate area and keep unnecessary and unprotected personnel from entering the spill area.</p> <p>Avoid personal contact and breathing vapors or mists. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.</p>
<b>Environmental precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Methods and material for containment and cleaning up</b>	<p>Containment: Contain spills with an inert absorbent material such as soil, sand or oil dry.</p> <p>Cleaning Up: Absorb spill with inert material (eg., dry sand or earth), then place in a chemical waste container. After removal,</p>

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flush spill area with soap and water to remove trace residue.

## 7 HANDLING AND STORAGE

### Precautions for safe handling

When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions. Wash thoroughly after handling. Avoid contact with eyes and skin. Review and implement appropriate technical and procedural wastewater 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 at controlled room temperature 20 to 25°C (68 to 77°F). Protect from freezing.

**Incompatible Materials:** No special restrictions on storage with other products.

## 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

### CONTROL PARAMETERS:

#### Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL
Magnesium Sulfate Heptahydrate	10 mg/m <sup>3</sup> TWA (Inhalable fraction) 3 mg/m <sup>3</sup> TWA (Respirable fraction)	15 mg/m <sup>3</sup> TWA (Total dust) 5 mg/m <sup>3</sup> TWA (Respirable fraction)
Sulfuric Acid	0.1 mg/m <sup>3</sup> (ST) 3 mg/m <sup>3</sup>	0.2 mg/m <sup>3</sup> (Thor.)
Sodium Hydroxide	(C) 2 mg/m <sup>3</sup>	(C) 2 mg/m <sup>3</sup>

### EXPOSURE CONTROLS: Engineering controls, individual protection measures and PPE

**Respiratory:** 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

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half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.

**Eyes / Face:** Chemical splash goggles. Wear a face shield also when splash hazard exists.

**Skin and Body:** Protective laboratory coat, apron, or disposable garment recommended.

**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.

**General Considerations:** Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

## 9 PHYSICAL AND CHEMICAL PROPERTIES

Properties:	Values	Remarks
<b>Physical State:</b>	Liquid Solution	
<b>Appearance:</b>	Clear Solution	
<b>Color:</b>	Colorless	
<b>Upper Flammability Limit:</b>	--	Not Available
<b>Lower Flammability Limit:</b>	--	Not Available
<b>Explosive Limit</b>	--	Not Available
<b>Odor:</b>	Odorless	
<b>Vapor Pressure:</b>	--	Not Available
<b>Odor Threshold:</b>	Not Applicable	
<b>Vapor Density:</b>	--	Not Available
<b>pH</b>	3.5-6.5	
<b>Relative Density</b>	--	Not Available
<b>Melting Point</b>	--	Not Available
<b>Freezing Point</b>	--	Not Available
<b>Solubility</b>	Soluble in Water	
<b>Initial Boiling Point:</b>	--	Not Available
<b>Boiling Range:</b>	--	Not Available
<b>Flash Point:</b>	--	Not Available
<b>Evaporation Rate:</b>	--	Not Available
<b>Flammability:</b>	--	Not Available
<b>Partition Coefficient: n-octanol / water:</b>	--	Not Available
<b>Auto-ignition Temperature:</b>	--	Not Available
<b>Decomposition Temperature:</b>	--	Not Available

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<b>Viscosity:</b>	--	Not Available
<b>Density (g/mL)</b>	1.019 - 1.021	
<b>Kinematic Viscosity:</b>	--	Not Available
<b>Dynamic Viscosity:</b>	--	Not Available
<b>Explosive Properties:</b>	--	Not Available
<b>Oxidizing Properties:</b>	--	Not Available
<b>Softening Point:</b>	--	Not Available
<b>Molecular Weight:</b>	Mixture	Not Applicable
<b>VOC Content (%):</b>	--	Not Available
<b>Specific Gravity:</b>	--	Not Available

## 10 STABILITY AND REACTIVITY

<b>Reactivity:</b>	No dangerous reaction known under conditions of normal use.
<b>Chemical Stability:</b>	Stable under normal temperatures and pressures.
<b>Possibility of Hazardous reactions:</b>	None under normal processing.
<b>Conditions to avoid:</b>	No conditions producing hazardous situations known.
<b>Incompatible Materials:</b>	Avoid contact with: Alcohols, Calcium,
<b>Hazardous decomposition products:</b>	Thermal decomposition products include oxides sulfur
<b>Hazardous Polymerization:</b>	No information available.

## 11 TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure:

<b>Product Information:</b>	Adverse effects associated with therapeutic use include flushing, sweating, decrease in blood pressure (hypotension), circulatory failure, central nervous system depression.
<b>Acute Toxicity:</b>	Eye, skin, and respiratory irritation may occur.

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**ACUTE TOXICITY**

CHEMICAL NAME	Oral LD50	Dermal LD50	Inhalation LC50
Magnesium Sulfate Heptahydrate	Rat: 5000mg / kg Mouse: 3000 mg / kg	Rat: 1200 mg / kg	Not determined
Dextrose	Rat: 25800 mg / kg	/	/
Sulphuric Acid	Rat: 2140 mg / kg	/	Rat: 320mg / m <sup>3</sup> / 2h
Sodium Hydroxide	Mouse: 660 mg/kg Rat: 4090 mg / kg	Rabbit: 500mg/24h mild	Mouse: 6600 mg/kg Rat: 2300 mg / m <sup>3</sup> / 2h

Note: As a result of the physical presentation of the product, the risk to health is expected to be very low under normal conditions of handling and use. The following health hazard assessment is based on a consideration of the composition of this product.

**Information on toxicological effects:**

**Delayed, Immediate or Chronic Effects from Short- and Long-Term Exposure**

- Inhalation:** The material will irritate the upper respiratory tract.
- Ingestion:** Symptoms may include flushing of the skin, thirst, hypotension, loss of reflexes, and respiratory depression.
- Skin:** Irritating to skin. The symptoms may include redness, itching and swelling.
- Eye:** Irritating to eyes. On eye contact this product will cause tearing, stinging, blurred vision and redness.
- Chronic Effects:** None known.
- Carcinogenicity:** Studies with Magnesium Sulfate in 5% Dextrose Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential or effects on fertility.
- Tests on bacterial or mammalian cell cultures did not show mutagenic effects.
- The International Agency for Research on Cancer (IARC) and the United States National Toxicology Program (NTP) have classified 'occupational

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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. Classification of Sulfuric acid (IARC) Group 1 (Carcinogenic to Humans)

**Reproduction & Development Toxicity:**

FETAL HARM: Continuous administration of magnesium sulfate beyond 5-7 days to pregnant women can lead to hypocalcemia and bone abnormalities in the developing fetus. These bone abnormalities include skeletal demineralization and osteopenia. In addition, cases of neonatal fracture have been reported. The shortest duration of treatment that can lead to fetal harm is not known. Magnesium sulfate should be used during pregnancy only if clearly needed. If magnesium sulfate is given for treatment of preterm labor, the woman should be informed that the efficacy and safety of such use have not been established and that use of magnesium sulfate beyond 5-7 days may cause fetal abnormalities.

**STOT: Single Exposure:**

Evaluation of available data suggests that this material is not an STOT-SE toxicant

**STOT: Repeated Exposure:**

Serious systemic effects may develop when ingested in medicinal use, especially in individuals with impaired renal function. Such effects would not result from normal industrial handling. Signs and symptoms of excessive exposure may include nausea and vomiting, abdominal discomfort or diarrhea

**Aspiration Hazard:**

Not Applicable.

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## 12 ECOLOGICAL INFORMATION

<b>AQUATIC TOXICITY:</b>	Material is practically non-toxic to aquatic organisms on an acute basis (LC50/EC50/EL50/LL50 >100 mg/L in the most sensitive species tested).
<b>PERSISTENCE AND DEGRADABILITY:</b>	Inorganic salt which ionizes in water
<b>BIOACCUMULATION:</b>	Not Available
<b>OTHER ADVERSE EFFECTS:</b>	Not Available

## 13 DISPOSAL CONSIDERATIONS

### WASTE TREATMENT METHODS:

<b>DISPOSAL OF WASTES:</b>	Dispose of waste in accordance with local, state and federal regulations
<b>CONTAMINATED PACKAGING:</b>	The container or packaging must be cleaned and rendered incapable of holding any substance. It can then be disposed of in a manner consistent with that of the substance it contained. In this instance the packaging can be disposed through a commercial waste collection service. Alternatively, the container or packaging can be recycled if the hazardous residues have been thoroughly cleaned or rendered nonhazardous. Do not reuse container.
<b>US EP WASTE NUMBER:</b>	Not Applicable
<b>CALIFORNIA HAZARDOUS WASTE CODES:</b>	Not Applicable

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## 14 TRANSPORT INFORMATION

### **REGULATORY ORGANIZATIONS:**

DOT: Not Regulated

IATA: Not regulated as a dangerous good

ICAO: Not Regulated

IMDG: Not regulated as a dangerous good

RID: Not Regulated

ADR: Not Regulated

ADG: Not Regulated

*Special Precautions: NONE*

## 15 REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

### **US State Regulations and Right to Know Regulations**

<b>SARA 311/312 Hazards:</b>	This product is not hazardous chemical under 29CFR 1910.1200 and therefore not covered by Title III of SARA
<b>SARA 302:</b>	No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302
<b>SARA 313:</b>	This material does not contain any chemical components with known CAS numbers that exceed the threshold (de minimis) reporting levels established by SARA Title III, Section 313
<b>California Prop 65:</b>	Not listed
<b>OSHA Substance Specific</b>	No

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## 16 OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PUROPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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**END OF SAFETY DATA SHEET**

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