



AMERICAN REGENT, INC.

**MATERIAL SAFETY DATA SHEET****Section 1: PRODUCT AND COMPANY INFORMATION**

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**PRODUCT NAME: Magnesium Sulfate Injection, USP****PRODUCT CODE (NDC): 50%: 0517-2602-25, 0517-2610-25, 0517-2650-25****Section 2: HAZARDS IDENTIFICATION****EMERGENCY OVERVIEW**

Appearance / Odor	Clear, colorless, odorless solution.
<b>WARNING!</b>	
Skin, eye and respiratory irritant	May cause irritation of the eyes, skin and respiratory tract.
Toxicity to fish/aquatic organisms	Product is not known to be toxic to fish.
<i>Potential Health Effects: See Section 11 for more information</i>	
Likely Routes of Exposure	Eye contact, skin contact and inhalation.
Eye	Causes irritation of the eye.
Skin	May cause irritation of the skin.
Inhalation	May cause irritation of the upper and lower respiratory tract.
Ingestion	May cause irritation of the gastrointestinal tract.
Skin Absorption	Not absorbed through the skin.
Medical Conditions Aggravated by Exposure	Personnel with impaired kidneys or cardiovascular system.
Target Organs	Eyes, kidneys, respiratory tract and heart.

*continued on next page*

<b>Section 2: HAZARDS IDENTIFICATION (continued)</b>	
<i>Potential Environmental Effects: See Section 12 for more information</i>	This product is not known to be toxic to fish.
This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	
This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).	

<b>Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS</b>		
Component	CAS Number	Percentage (%) by Weight
Magnesium Sulfate	10034-99-8	50.0 percent
Sodium Hydroxide	1310-73-2	used for pH adjustment
Sulfuric Acid	7664-93-9	used for pH adjustment
Water for Injection	7732-18-5	50.0 percent

<b>Section 4: FIRST AID MEASURES</b>	
Eye Contact	Causes irritation. Flush for 15 minutes with copious quantities of water. Seek medical attention.
Skin Contact	May cause irritation. Remove contaminated clothing. Flush area with copious quantities of water for 15 minutes. Seek medical attention.
Inhalation	May cause irritation of respiratory tract. Remove person to fresh air. Remove contaminated clothing. Seek medical attention.
Ingestion	May cause irritation. Flush mouth out with water. Seek medical attention.
Injection	See prescribing information.
Note to Physicians	Adverse reactions to this product may result in flushing, sweating, hypothermia and ultimately, respiratory depression. See prescribing information.

<b>Section 5: FIRE FIGHTING MEASURES</b>	
Suitable Extinguishing Media	Water spray, foam, dry chemical or Carbon Dioxide (CO <sub>2</sub> ). <b>Caution:</b> CO <sub>2</sub> will displace air in confined spaces and may cause an oxygen deficient atmosphere.
Unsuitable Extinguishing Media	None.
Hazardous Combustion Products	When heated, Magnesium Sulfate solution thermally decomposes to form toxic vapors. (i.e. oxides of Sulfur and Magnesium).
<u>Protection for Firefighters:</u> Magnesium Sulfate solution thermally decomposes to form toxic vapors. Vapors may be irritating to eyes and skin and toxic to respiratory tract. Firefighters are to wear self-contained breathing apparatus (SCBA) and full turn out gear (Bunker gear). Cool containers with water spray and use caution when approaching.	

<b>Section 6: ACCIDENTAL RELEASE MEASURES</b>	
Personnel Precautions	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Environmental Precautions	This material is not considered a water pollutant. However, it is recommended to prevent spilled or leaking material from entering waterways. Minimize the use of water to prevent environmental contamination.
Methods of Containment	Absorb material with suitable materials such as clay absorbent or absorbent pads for aqueous solutions.
Methods of Clean Up	Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.
Other Information	A spill of this material does not need to be reported to the National Response Center.

<b>Section 7: HANDLING AND STORAGE</b>	
<u>Handling:</u>	
As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes or clothing. Do not mix with other drugs.	
Use in a well ventilated area. Wash thoroughly after handling.	
<u>Storage:</u>	
Store in a well ventilated area. Keep containers closed when not in use. Product residue may remain in empty containers. Observe all label precautions until container is cleaned, discarded or destroyed.	

<b>Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION</b>			
Exposure Guidelines	OSHA PEL	ACGIH TLV	OTHER
Magnesium Sulfate	Not listed	Not listed	
Sodium Hydroxide	2 milligrams / cubic meter - 8 hour TWA	2 milligrams / cubic meter - Ceiling	
Sulfuric Acid	1 milligram per cubic meter	0.2 milligrams per cubic meter	
Water for Injection	Not listed	Not listed	
Personal Protective Equipment		Description	
Ventilation		Local exhaust or general ventilation is recommended.	
Respiratory Protection		Under normal conditions of product use, respiratory protection is not required. When required, use a NIOSH approved air purifying respirator with P-100 / acid gas cartridges.	
Eye Protection		Wear ANSI approved chemical splash goggles or safety glasses.	
Skin Protection		When administering this product to patients, wear nitrile or latex gloves. Use Tyvek™ SL or equivalent coveralls, PVC booties and nitrile gloves for clean up activities.	

<b>Section 9: PHYSICAL AND CHEMICAL PROPERTIES</b>	
Color	A clear, colorless solution
Odor / Odor Threshold	Odorless
Physical State	Liquid
pH	5.5 to 7.0
Freezing Point	Approximately 32 degrees Fahrenheit
Boiling Point	Approximately 212 degrees Fahrenheit
Flash Point	Not applicable
Evaporation Rate	Not applicable
Flammability	Nonflammable, noncombustible
Upper Flammable Limit	Not applicable
Lower Flammable Limit	Not applicable
Vapor Pressure	Not applicable
Vapor Density	Not applicable
Specific Gravity	Approximately 1.2
Solubility (water)	Freely soluble in water
Partition Coefficient	Not applicable
Auto-ignition Temperature	Not applicable
Percent Volatile	0 percent
Volatile Organic Compounds (%)	0 percent

<b>Section 10: STABILITY AND REACTIVITY</b>	
Stability	Stable.
Conditions to Avoid	Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames, thermally decomposes to form toxic vapors.
Incompatible Materials	Reactive with strong oxidizers, Alcohols, Lead, Barium and Calcium.
Hazardous Decomposition Products	Magnesium and Sulfur oxides may be released by thermal decomposition.
Possibility of Hazardous Reactions	Hazardous polymerization will not occur.

<b>Section 11: TOXICOLOGY INFORMATION</b>	
<b>Acute Effects</b>	
Oral (LD <sub>50</sub> )	LD <sub>50</sub> : 3600 mg/kg oral - rat
Subcutaneous (LD <sub>50</sub> )	No data available
Intraperitoneal (LD <sub>50</sub> )	No data available
Dermal (LD <sub>50</sub> )	No data available
Inhalation	Respiratory irritation is possible.
Eye Irritation	Causes eye irritation.
Skin Irritation	Skin irritation is possible.
Sensitization	No data available regarding worker sensitivity to Magnesium Sulfate.
<b>Chronic Effects</b>	
Organ Systems	Prolonged exposure may damage the kidneys, heart and upper respiratory tract.
Carcinogenicity	Magnesium Sulfate is not considered carcinogenic. No adequate and well controlled studies involving the carcinogenic effects of Magnesium Sulfate in humans have been conducted. Sulfuric acid is classified as a carcinogen.
Mutagenicity	Magnesium Sulfate is not considered mutagenic. No adequate and well controlled studies involving the mutagenic effects of Magnesium Sulfate in humans have been conducted.
Reproductive Effects	Magnesium Sulfate is not considered a reproductive toxin. No adequate and well controlled studies involving the reproductive effects of Magnesium Sulfate in humans have been conducted.

<b>Section 11: TOXICOLOGY INFORMATION (continued)</b>	
Developmental Effects	Magnesium Sulfate is not considered teratogenic. No adequate and well controlled studies involving the teratogenic effects of Magnesium Sulfate in humans have been conducted. Classified as Pregnancy Category C.
<b>Section 12: ECOLOGICAL INFORMATION</b>	
Ecotoxicity	No data available.
Persistence / Degradability	Short term products of biodegradation are not likely. Long term degradation products may arise.
Bioaccumulation / Accumulation	No applicable bioaccumulation is expected in the environment.
Mobility in Environment	Appreciable volatilization is not expected into the air. Can move freely through the aquatic environment.
<b>Section 13: DISPOSAL CONDITIONS</b>	
Disposal	Do not mix with other substances. Dispose of in accordance with Federal, state and local regulations. Contact your state or local government environmental and / or sanitation department for guidance on disposal.
<b>Section 14: TRANSPORTATION INFORMATION</b>	
Regulatory Agency	Shipping Description
US DOT (ground)	Not considered a DOT regulated material - Non hazardous for shipment.
Canadian TDG (ground)	See US DOT.
IATA (air)	Not considered a DOT regulated material - Non hazardous for shipment.
<b>Section 15: REGULATORY INFORMATION</b>	
STATE RIGHT TO KNOW	Refer to the applicable state to determine applicability.
California Safe Drinking Water & Toxic Enforcement Act (Prop 65)	This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins under California Proposition 65.
RTECS Number	OM4508000
TSCA	8b Inventory - Not listed
NFPA Rating	Health - 1, Fire - 0, Reactivity - 0
WHMIS (Canada)	Not controlled

**Section 16: OTHER INFORMATION**

Magnesium Sulfate Injection, USP is indicated in the following conditions:

Convulsions (treatment) – Intravenous Magnesium Sulfate is indicated for immediate control of life-threatening convulsions in the treatment of severe toxemias (pre-eclampsia and eclampsia) of pregnancy and in the treatment of acute nephritis in children.

Hypomagnesemia (prophylaxis and treatment) – Magnesium Sulfate is indicated for replacement therapy in Magnesium deficiency, especially in acute hypomagnesemia accompanied by signs of tetany similar to those of hypocalcemia.

Magnesium Sulfate is also used to prevent or treat Magnesium deficiency in patients receiving total parenteral nutrition.

Tetany, uterine (treatment) – Magnesium Sulfate is indicated in uterine tetany as a myometrial relaxant.

Refer to Luitpold / American Regent's prescribing information for further information at [http://www.americanregent.com/product\\_index.asp](http://www.americanregent.com/product_index.asp)

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