MAGNESIUM CHLORIDE INJECTION 200MG/ML

SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

Product Identifier

Product name: Magnesium Chloride Injection 200mg/mL

Intended Use Of The Product

Use of the substance/preparation: Pharmaceutical. Magnesium Chloride injection is indicated as an electrolyte replenisher in magnesium deficiencies. Use only as directed. Refer to product insert for usage instructions and product information.

Name, Address, And Telephone Of The Responsible Party

Supplier:
Mylan Institutional LLC
1718 Northrock Court
Rockford, IL 61003 USA
1-888-258-4199
www.mylan.com

Manufacturer:
Mylan Teronata
Galway, Ireland

Emergency Telephone Number

Emergency number : +1 877-446-3679

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

Classification of the Substance or Mixture

Classification (GHS-US)

Not classified

Label Elements

GHS-US labeling No labeling applicable

Other Hazards Not available

Unknown acute toxicity (GHS-US) Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Magnesium chloride, hexahydrate	(CAS No.) 7791-18-6	-	Not classified
Benzyl alcohol	(CAS No.) 100-51-6	1	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 3 (Inhalation: vapour), H331

Additional Information: Hydrochloric acid and/or sodium hydroxide has been added for pH adjustment.

Full text of H-phrases: see section 16

4. FIRST AID MEASURES

Description Of First Aid Measures

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.
Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

Most Important Symptoms And Effects Both Acute and Delayed

Inhalation: May cause respiratory irritation
Skin Contact: May cause mild skin irritation.
Eye Contact: May cause eye irritation.
Ingestion: May cause a light irritation of the linings of the mouth, throat, and gastrointestinal tract
Injection: Adverse reactions with Magnesium Chloride reported are flushing, sweating, sharply lowered blood pressure, hypothermia, stupor and ultimately respiratory depression.

Indication Of Any Immediate Medical Attention And Special Treatment Needed

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

5. FIREFIGHTING MEASURES

Extinguishing Media

Suitable extinguishing media: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media: None known.

Special Hazards Arising From the Substance or Mixture

Fire hazard: Not considered flammable but may burn at high temperatures
Explosion hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.

Advice for Firefighters

Precautionary measures fire: Exercise caution when fighting any chemical fire.
Firefighting instructions: Use water spray/fog for cooling exposed containers.
Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.
Hazardous Combustion Products: Carbon oxides (CO, CO_2). When heated, magnesium chloride solution thermally decomposes to form toxic vapors. (Magnesium oxides and halogenated compounds).
Other information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment And Emergency Procedures

General measures: Avoid all eye and skin contact and do not breathe vapor and mist.

For Non-Emergency Personnel

Protective equipment: Use appropriate personal protection equipment (PPE).
Emergency procedures: Evacuate unnecessary personnel.

For Emergency Personnel

Protective equipment: Equip cleanup crew with proper protection.

Environmental Precautions

Prevent entry to sewers and public waters.

Methods And Material For Containment And Cleaning Up

For containment: Absorb and/or contain spill with inert material, then place in suitable container.
Methods for cleaning up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

Reference To Other Sections

See heading 8, Exposure Controls and Personal Protection.

7. HANDLING AND STORAGE

Precautions For Safe Handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Hygiene measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

Conditions For Safe Storage, Including Any Incompatibilities

Storage conditions: Store in a dry, cool place. Keep away from heat, sparks, flames and direct sunlight.

Incompatible materials: Strong acids, bases, and oxidizers.
Storage temperature: 15-30°C (59-86°F)
Special rules on packaging: Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

Specific End Use(s)

Pharmaceutical. Magnesium Chloride injection is indicated for use as an electrolyte replenisher in magnesium deficiencies. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters

No Occupational Exposure Limits have been established for the product or its components.

Exposure Controls

Appropriate engineering controls: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Personal protective equipment: Not generally required. The use of personal protective equipment may be necessary as conditions warrant.
Hand protection: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
Eye protection: In laboratory, medical or industrial settings, or operations in which vapors or mists will be generated, safety glasses with side shields are recommended..
Skin and body protection: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.
Respiratory protection: When manufacturing or handling product in large quantities and vapors or mists may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH approved respirators for protection should be used if respirators are found to be necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information On Basic Physical And Chemical Properties

Physical state	:	Liquid
Appearance	:	Clear, colorless
Odor	:	Not available
Odor threshold	:	Not available
pH	:	Not available
Relative evaporation rate (butyl acetate=1)	:	Not available
Melting/Freezing point	:	Not available
Boiling point	:	Not available
Flash point	:	Not available
Auto-ignition temperature	:	Not available
Decomposition Temperature	:	Not available
Flammability (solid, gas)	:	Not available
Upper/Lower flammable limit	:	Not available
Vapor pressure	:	Not available
Relative vapor density at 20 °C	:	Not available
Relative density	:	Not available
Specific gravity	:	Not available
Solubility	:	Not available
Log Pow/Kow	:	Not available
Viscosity (kinematic, dynamic)	:	Not available
Explosion data - sensitivity to mechanical impact	:	Not available
Explosion data - sensitivity to static discharge	:	Not available

10. STABILITY AND REACTIVITY

Reactivity Hazardous reactions will not occur under normal conditions.
Chemical Stability Stable under recommended handling and storage conditions (see section 7).
Possibility Of Hazardous Reactions Hazardous polymerization will not occur.
Conditions To Avoid Direct sunlight. Extremely high or low temperatures.
Incompatible Materials Strong acids. Strong bases. Strong oxidizers.
Hazardous Decomposition Products Carbon oxides (CO, CO_2). When heated, Magnesium Chloride solution thermally decomposes to form toxic vapors. (Magnesium oxides and halogenated compounds).

11. TOXICOLOGICAL INFORMATION

Information On Toxicological Effects - Product

Acute toxicity: Not classified
LD50 and LC50 Data Not available
Skin corrosion/irritation: Not classified
Serious eye damage/irritation: Not classified
Respiratory or skin sensitization: Not classified
Germ cell mutagenicity: Not classified
Teratogenicity: Not available
Carcinogenicity: Not classified
Specific target organ toxicity (repeated exposure): Not classified
Reproductive toxicity: Not classified
Specific target organ toxicity (single exposure): Not classified
Aspiration hazard: Not classified

Information On Toxicological Effects - Ingredient(s)

LD50 and LC50 Data

Magnesium chloride, hexahydrate (7791-18-6)	
LD50 oral rat	8100 mg/kg

Benzyl alcohol (100-51-6)	
LD50 oral rat	1230 mg/kg
LD50 dermal rat	1700 mg/kg
LD50 dermal rabbit	2000 mg/kg
LD50 Intravenous Rat	53 mg/kg
LC50 inhalation rat (mg/l)	8.8 mg/l (Exposure time: 4 h)

Benzyl alcohol (100-51-6)	
National Toxicity Program (NTP) Status	3

12. ECOLOGICAL INFORMATION

Toxicity

Benzyl alcohol (100-51-6)	
LC50 fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	23 mg/l (Exposure time: 48 h - Species: water flea)
EC50 other aquatic organisms 1	35 mg/l (Exposure time: 3 h - Species: Anabaena variabilis)
LC50 fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])

Persistence And Degradability Not available

Bioaccumulative Potential

Benzyl alcohol (100-51-6)	
Log Pow	1.1

13. DISPOSAL CONSIDERATIONS

Waste disposal recommendations: Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.

Additional information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

14. TRANSPORT INFORMATION

In accordance with ICAO/IATA/DOT/TDG

UN Number Not regulated for transport

UN Proper Shipping Name Not regulated for transport

15. REGULATORY INFORMATION

US Federal regulations

Benzyl alcohol (100-51-6)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

US State regulations

Benzyl alcohol (100-51-6)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Water Quality - Ground Water Quality Criteria
U.S. - New Jersey - Water Quality - Practical Quantitation Levels (PQLs)
U.S. - Pennsylvania - RTK (Right to Know) List

Canadian regulations

Magnesium Chloride Injection	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria

Magnesium chloride, hexahydrate (7791-18-6)	
WHMIS Classification	Uncontrolled product according to WHMIS classification criteria

Benzyl alcohol (100-51-6)	
Listed on the Canadian DSL (Domestic Substances List) inventory. Listed on the Canadian Ingredient Disclosure List – 1%	
WHMIS Classification	Class B Division 3 - Combustible Liquid Class D Division 2 Subdivision B - Toxic material causing other toxic effects

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

16. OTHER INFORMATION

Indication of changes : 06/10/2014

Data sources : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Other information : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

GHS Full Text Phrases:

Acute Tox. 3 (Inhalation:vapour)	Acute toxicity (inhalation:vapour) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Flam. Liq. 4	Flammable liquids Category 4
H302	Harmful if swallowed
H312	Harmful in contact with skin
H331	Toxic if inhaled

Party Responsible For The Preparation Of This Document:
Mylan Global Environmental, Health, and Safety Department
Phone Number: 304-599-2595

This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.
To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

North America Mylan Pharmaceuticals