



SAFETY DATA SHEET

Revision date 17-Feb-2020

Version 1.11

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Magnesium Sulfate Injection, USP (Hospira Inc.)
Product Code(s) PZ03095
Trade Name: Magnesium Sulfate Injection, USP
Chemical Family: Not determined

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as electrolyte replacement anticonvulsant

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
E-mail address pfizer-MSDS@pfizer.com

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not classified as hazardous

2.2. Label elements

Signal word Not Classified

Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings 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

3.1 Substances

Hazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
SULPHURIC ACID ... %	231-639-5	7664-93-9	**	Skin Corr. 1A (H314)	
Sodium hydroxide	215-185-5	1310-73-2	**	Skin Corr.1A (H314)	

NonHazardous

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Water	231-791-2	7732-18-5	50	Not Listed	
Magnesium sulfate heptahydrate	Not Listed	10034-99-8	<=50	Not Listed	

Full text of H- and EUH-phrases: see section 16

Additional information ** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Move to fresh air. If discomfort persists, get medical attention.
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	Clean mouth with water and drink afterwards plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

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Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media As for primary cause of fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Not applicable.

Hazardous combustion products Formation of toxic gases is possible during heating or fire. Emits oxides of sulfur under combustion.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Keep away from incompatible materials.

Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on 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.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

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7.3. Specific end use(s)

Specific use(s) Pharmaceutical product used as. electrolyte replacement, anticonvulsant.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

SULPHURIC ACID ... %

ACGIH TLV	0.2 mg/m ³
Austria	0.1 mg/m ³ STEL 0.2 mg/m ³
Bulgaria	0.05 mg/m ³
Czech Republic	1 mg/m ³ 0.05 mg/m ³ Ceiling: 2 mg/m ³
Denmark	0.05 mg/m ³
Estonia	1 mg/m ³
Finland	0.05 mg/m ³ STEL: 0.1 mg/m ³
France	0.05 mg/m ³
Germany	0.1 mg/m ³ Ceiling / Peak: 0.1 mg/m ³
Germany	0.1 mg/m ³
Hungary	0.05 mg/m ³
Ireland	0.05 ppm STEL: 0.15 ppm
Italy	0.05 mg/m ³
Ceiling Limit Value	1 mg/m ³
Latvia	0.05 mg/m ³
Netherlands	0.05 mg/m ³
Poland	0.05 mg/m ³
Romania	0.05 mg/m ³
Russia	MAC: 1 mg/m ³ Skin
Slovakia	0.05 mg/m ³
Spain	0.05 mg/m ³
Switzerland	0.1 mg/m ³ STEL: 0.2 mg/m ³
OSHA PEL	1 mg/m ³ (vacated) TWA: 1 mg/m ³
United Kingdom	TWA: 0.05 mg/m ³ STEL: 0.15 mg/m ³

Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m ³
ACGIH TLV	Ceiling: 2 mg/m ³
Austria	2 mg/m ³ STEL 4 mg/m ³
Bulgaria	2.0 mg/m ³
Czech Republic	1 mg/m ³ Ceiling: 2 mg/m ³
Denmark	Ceiling: 2 mg/m ³
Estonia	1 mg/m ³ STEL: 2 mg/m ³
Finland	Ceiling: 2 mg/m ³
France	2 mg/m ³

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Hungary	2 mg/m ³ STEL: 2 mg/m ³
Ireland	STEL: 2 mg/m ³
Ceiling Limit Value	2 mg/m ³
Latvia	0.5 mg/m ³
Poland	STEL: 1 mg/m ³ 0.5 mg/m ³
Romania	1 mg/m ³ STEL: 3 mg/m ³
Slovakia	2 mg/m ³
Spain	STEL: 2 mg/m ³
Switzerland	2 mg/m ³
OSHA PEL	STEL: 2 mg/m ³ 2 mg/m ³
United Kingdom	(vacated) Ceiling: 2 mg/m ³ STEL: 2 mg/m ³

8.2. Exposure controls

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.
Environmental exposure controls	No information available.
Personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Eye/face protection	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.).
Hand protection	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.).
Skin and body protection	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.).

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Colourless
Molecular formula (MF):	Mixture
Molecular weight	Mixture
Odor	No data available.
Odor threshold	No data available

<u>Property</u>	<u>Values</u>
pH	3.5-7.0

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Melting point / freezing point	No data available
Boiling point / boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Explosive properties	No data available
Oxidizing properties	None
9.2. Other information	
Liquid Density	No data available
Bulk density	No data available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid None known.

10.5. Incompatible materials

Incompatible materials None known.

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition products include. oxides of sulfur.

Section 11: TOXICOLOGICAL INFORMATION

11.1. 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.

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Acute Toxicity: (Species, Route, End Point, Dose)

Magnesium sulfate heptahydrate

Rat Oral LDmin. 5000 mg/kg
Mouse Oral LDmin. 3000 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
SULPHURIC ACID ... %	= 2140 mg/kg (Rat)	-	85 - 103 mg/m ³ (Rat) 1 h
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Magnesium sulfate heptahydrate

Fertility and Embryonic Development Rat Oral 450 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Magnesium sulfate heptahydrate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogenicity

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
NTP

Group 1 (Carcinogenic to Humans)
Known Human Carcinogen

Section 12: ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties have not been investigated. Releases to the environment should be avoided.

12.1. Toxicity

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Water

Daphnia magna (Water Flea) OECD 21 Day(s) EC50 66 mg/l Reproduction

12.2. Persistence and degradability

Persistence and degradability

No information available.

12.3. Bioaccumulative potential

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Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical Name	PBT and vPvB assessment
SULPHURIC ACID ... %	The substance is not PBT / vPvB PBT assessment does not apply
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. 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

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

Magnesium sulfate heptahydrate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed

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EINECS	Not Listed
AICS	Present
SULPHURIC ACID ... %	
CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	1000 lb
California Proposition 65	carcinogen 3/14/2003
TSCA	Present
EINECS	231-639-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 6
Sodium hydroxide	
CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

Data Sources: Publicly available toxicity information.

Reason for revision Updated Section 12 - Ecological Information.

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Prepared By Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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