



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 04-Aug-2016

Version: 1.0

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

### Product Identifier

**Material Name:** Magnesium Sulfate in 5% Dextrose Injection, USP (Hospira Inc.)

**Trade Name:** Magnesium Sulfate in 5% Dextrose Injection, USP

**Chemical Family:** Not determined

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as anticonvulsant

### 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

### Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

### Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### Label Elements

**Signal Word:** Not Classified

**Hazard Statements:** 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.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
SULPHURIC ACID ... %	7664-93-9	231-639-5	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Magnesium sulfate heptahydrate	10034-99-8	Not Listed	Not Listed	1-2
Water for Injection	7732-18-5	231-791-2	Not Listed	93
Dextrose, monohydrate	5996-10-1	Not Listed	Not Listed	5

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

**For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16**

### 4. FIRST AID MEASURES

**Description of 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**

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

### 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 fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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### 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. Clean up operations should only be undertaken by trained personnel.

### 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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m <sup>3</sup>
Australia PEAK	2 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	2.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
Estonia OEL - TWA	1 mg/m <sup>3</sup>
France OEL - TWA	2 mg/m <sup>3</sup>
Greece OEL - TWA	2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Japan - OELs - Ceilings	2 mg/m <sup>3</sup>
Latvia OEL - TWA	0.5 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	2 mg/m <sup>3</sup>
Poland OEL - TWA	0.5 mg/m <sup>3</sup>
Slovakia OEL - TWA	2 mg/m <sup>3</sup>
Slovenia OEL - TWA	2 mg/m <sup>3</sup>
Sweden OEL - TWAs	1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	2 mg/m <sup>3</sup>

#### SULPHURIC ACID ... %

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ACGIH Threshold Limit Value (TWA)	0.2 mg/m <sup>3</sup>
Australia STEL	3 mg/m <sup>3</sup>
Australia TWA	1 mg/m <sup>3</sup>
Austria OEL - MAKs	0.1 mg/m <sup>3</sup>
Belgium OEL - TWA	0.2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	0.05 mg/m <sup>3</sup>
Cyprus OEL - TWA	0.05 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
	0.05 mg/m <sup>3</sup>
Denmark OEL - TWA	0.05 mg/m <sup>3</sup>
Estonia OEL - TWA	1 mg/m <sup>3</sup>
Finland OEL - TWA	0.05 mg/m <sup>3</sup>
France OEL - TWA	0.05 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	0.1 mg/m <sup>3</sup>
Germany (DFG) - MAK	0.1 mg/m <sup>3</sup>
Greece OEL - TWA	0.05 mg/m <sup>3</sup>
Hungary OEL - TWA	0.05 mg/m <sup>3</sup>
Ireland OEL - TWAs	0.05 ppm
Italy OEL - TWA	0.05 mg/m <sup>3</sup>
Japan - OELs - Ceilings	1 mg/m <sup>3</sup>
Latvia OEL - TWA	0.05 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.05 mg/m <sup>3</sup>
Luxembourg OEL - TWA	0.05 mg/m <sup>3</sup>
Malta OEL - TWA	0.05 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.05 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	1 mg/m <sup>3</sup>
Poland OEL - TWA	0.05 mg/m <sup>3</sup>
Portugal OEL - TWA	0.05 mg/m <sup>3</sup>
Romania OEL - TWA	0.05 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.1 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.05 mg/m <sup>3</sup>
Spain OEL - TWA	0.05 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	0.1 mg/m <sup>3</sup>
Vietnam OEL - TWAs	1 mg/m <sup>3</sup>

#### 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.

##### 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.)

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid	<b>Color:</b>	Colourless
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	3.5-6.5
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**SULPHURIC ACID ... %**

No data available

**SODIUM HYDROXIDE**

No data available

**Magnesium sulfate heptahydrate**

No data available

**Water for Injection**

No data available

**Dextrose, monohydrate**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

**Possibility of Hazardous Reactions**

**Oxidizing Properties:** None

**Conditions to Avoid:** None known

**Incompatible Materials:** None known

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### 10. STABILITY AND REACTIVITY

**Hazardous Decomposition Products:** Thermal decomposition products include oxides of sulfur .

### 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.

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

##### Magnesium sulfate heptahydrate

Rat Oral LDmin. 5000 mg/kg

Mouse Oral LDmin. 3000mg/kg

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

##### Magnesium sulfate heptahydrate

Fertility and Embryonic Development Rat Oral 450 mg/kg/day NOEL 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

#### 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)

### 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

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### 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.

### 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.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Magnesium sulfate heptahydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

#### Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

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### 15. REGULATORY INFORMATION

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
<b>SULPHURIC ACID ... %</b>	
CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb
	454 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	1000 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	1000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	231-639-5
<b>Dextrose, monohydrate</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

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

**Data Sources:** Publicly available toxicity information.  
**Revision date:** 04-Aug-2016  
Product Stewardship Hazard Communication  
**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**