

### SECTION 1: IDENTIFICATION

#### 1.1. Product Identifier

**Product Form:** Solution

**Product Name:** Manganese Sulfate Injection, USP

**Product Code:** 0517-6410-25

#### 1.2. Intended Use of the Product

**Use of the substance/mixture:** Indicated for use as a supplement to intravenous solutions given for Total Parenteral Nutrition (TPN). Administration helps to maintain plasma levels and to prevent depletion of endogenous stores and subsequent deficiency symptoms.

#### 1.3. Name, Address, and Telephone of the Responsible Party

##### Company

Luitpold Pharmaceuticals, Inc.

One Luitpold Drive

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

[www.luitpold.com](http://www.luitpold.com)

#### 1.4. Emergency Telephone Number

**Emergency Number** : CHEMTREC 1-800-424-9300

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1. Classification of the Substance or Mixture

##### GHS-US classification

Not classified

#### 2.2. Label Elements

##### GHS-US Labeling

No labeling applicable

#### 2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions or liver or central nervous system disorders.

#### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Water for injection	(CAS No) 7732-18-5	99.97	Not classified
Manganese sulfate monohydrate	(CAS No) 10034-96-5	0.03	STOT RE 2, H373 Aquatic Chronic 2, H411
Sulfuric acid	(CAS No) 7664-93-9	Used to adjust pH	Skin Corr. 1A, H314 Eye Dam. 1, H318 Carc. 1A, H350 Aquatic Acute 3, H402

Full text of H-phrases: see section 16

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of First Aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical attention (show the label where possible). In the event of accidental injection, immediately call a poison center and seek medical attention.

**First-aid Measures After Inhalation:** Go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact:** Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

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**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

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

**Symptoms/Injuries:** None expected under normal conditions of use.

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** May cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause eye irritation.

**Symptoms/Injuries After Ingestion:** May cause irritation of the gastrointestinal tract.

**Chronic Symptoms:** None known.

## 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

### 5.2. 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.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any chemical fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Other Information:** Do not allow run-off from fire fighting to enter drains or water courses.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid breathing (vapor, mist, spray). Avoid all contact with skin, eyes, or clothing.

#### 6.1.1. For Non-emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Responders

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

### 6.3. Methods and Material for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Any vacuum used for clean-up must be equipped with high-efficiency (HEPA) filter. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

### 6.4. Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Use only as directed by the information identified in the package insert.

**Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Use only in well ventilated areas. Do not get in eyes, on skin, or on clothing. Avoid breathing vapors, mist, spray.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Store in a dry, well-ventilated place at 20° - 25°C (68° - 77°F) away from direct sunlight and incompatible materials.

**Incompatible Products:** Strong acids. Strong bases. Strong oxidizers.

### 7.3. Specific End Use(s) Pharmaceutical

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## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Sulfuric acid (7664-93-9)		
USA ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	0.2 mg/m <sup>3</sup> (thoracic fraction)
USA ACGIH	ACGIH chemical category	Suspected Human Carcinogen contained in strong inorganic acid mists
USA NIOSH	NIOSH REL (TWA) (mg/m <sup>3</sup> )	1 mg/m <sup>3</sup>
USA IDLH	US IDLH (mg/m <sup>3</sup> )	15 mg/m <sup>3</sup>
USA OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	1 mg/m <sup>3</sup>

### 8.2. 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

: Gloves. Protective goggles.



#### Hand Protection

: Wear chemically resistant protective gloves.

#### Eye Protection

: Chemical safety goggles.

#### Skin and Body Protection

: Wear suitable protective clothing. Wash contaminated clothing before reuse.

#### Respiratory Protection

: In case of inadequate ventilation wear respiratory protection.

#### Other Information

: When using, do not eat, drink or smoke.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: Clear, colorless
Odor	: Odorless
Odor Threshold	: No data available
pH	: 2.0 - 3.5
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: Odorless
Specific Gravity	: 1.0
Solubility	: Aqueous
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

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**9.2. Other Information** No additional information available

## SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. Conditions to Avoid:** Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames; thermally decomposes to form toxic vapors.
- 10.5. Incompatible Materials:** Strong acids. Strong bases. Strong oxidizers.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates: Trace oxides of sulfur and manganese.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information On Toxicological Effects

**Acute Toxicity:** Not classified

Sulfuric acid (7664-93-9)	
LD50 Oral Rat	2140 mg/kg
LC50 Inhalation Rat	510 mg/m <sup>3</sup> (Exposure time: 2 h)

**Skin Corrosion/Irritation:** Not classified (pH: 2.0 - 3.5)

**Serious Eye Damage/Irritation:** Not classified (pH: 2.0 - 3.5)

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

Sulfuric acid (7664-93-9)	
IARC group	1
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** May cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause eye irritation.

**Symptoms/Injuries After Ingestion:** May cause irritation of the gastrointestinal tract.

**Chronic Symptoms:** None known.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecology - General** : Not classified.

Sulfuric acid (7664-93-9)	
LC50 Fish 1	500 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])
LC 50 Fish 2	42 mg/l (Exposure time: 96 h - Species: Gambusia affinis [static])

**12.2. Persistence and Degradability** Not established

**12.3. Bioaccumulative Potential**

Sulfuric acid (7664-93-9)	
BCF fish 1	(no bioaccumulation)

**12.4. Mobility in Soil** No additional information available

**12.5. Other Adverse Effects**

**Other Information** : Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Ecology – Waste Materials:** Avoid release to the environment.

## SECTION 14: TRANSPORT INFORMATION

**14.1. In Accordance with DOT** Not regulated for transport

**14.2. In Accordance with IMDG** Not regulated for transport

**14.3. In Accordance with IATA** Not regulated for transport

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## SECTION 15: REGULATORY INFORMATION

### 15.1 US Federal Regulations

<b>Water (7732-18-5)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
<b>Sulfuric acid (7664-93-9)</b>	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
<b>SARA Section 302 Threshold Planning Quantity (TPQ)</b>	1000
<b>SARA Section 311/312 Hazard Classes</b>	Immediate (acute) health hazard Delayed (chronic) health hazard
<b>SARA Section 313 - Emission Reporting</b>	1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

### 15.2 US State Regulations

<b>Sulfuric acid (7664-93-9)</b>	
<b>U.S. - California - Proposition 65 - Carcinogens List</b>	WARNING: This product contains chemicals known to the State of California to cause cancer.
<b>Sulfuric acid (7664-93-9)</b>	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

<b>Revision Date</b>	: 11/10/2015
<b>Other Information</b>	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

### GHS Full Text Phrases:

Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Carc. 1A	Carcinogenicity Category 1A
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
STOT RE 2	Specific target organ toxicity (repeated exposure) Category 2
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H350	May cause cancer
H373	May cause damage to organs through prolonged or repeated exposure
H402	Harmful to aquatic life
H411	Toxic to aquatic life with long lasting effects

Refer to Luitpold/American Regent prescribing information for further information at:  
<http://www.americanregent.com/AllProducts.aspx>

The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.

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