

SECTION 1: IDENTIFICATION
1.1. Product Identifier

Product Name: Zinc Sulfate / Concentrated Zinc Sulfate Injection, USP

Product Code: 0517-6110-25, 0517-8105-25, 0517-8005-25, 0517-6103-25, 0517-6101-25, 0517-6101-01

Product Form: Solution

1.2. Intended Use of the Product

Use of the substance/mixture: Zinc sulfate injection, USP are indicated for use as a supplement to intravenous solutions given for TPN. Administration helps to maintain plasma levels and to prevent depletion of endogenous stores.

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

American Regent, Inc.

5 Ramsey Road

P.O. Box 9001

Shirley, NY 11967

1-800-645-1706

www.americanregent.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
Classification (GHS-US)

Eye Irrit. 2A H319

Aquatic Acute 3 H402

Aquatic Chronic 3 H412

Full text of H-phrases: see section 16

2.2. Label Elements
GHS-US Labeling
Hazard Pictograms (GHS-US) :


GH507

Signal Word (GHS-US) :

Warning

Hazard Statements (GHS-US) :

H319 - Causes serious eye irritation.

H402 - Harmful to aquatic life.

H412 - Harmful to aquatic life with long lasting effects.

Precautionary Statements (GHS-US) :

P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.

P273 - Avoid release to the environment.

P280 - Wear protective gloves, protective clothing, and eye protection.

P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. These products should not be given undiluted by direct injection into a peripheral vein because of the likelihood of infusion phlebitis. Exposure to this product may result in dizziness, lethargy, poor coordination, electrolyte imbalances, dehydration, abdominal pain, nausea and vomiting. Refer to package insert for more.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
3.1. Substance

Not applicable

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3.2. Mixture

| Name | Product Identifier | % | Classification (GHS-US) |
|---------------------------|--------------------|------------------------|---|
| Water for Injection | (CAS No) 7732-18-5 | 97.8 - 99.6 | Not classified |
| Zinc sulfate heptahydrate | (CAS No) 7446-20-0 | 0.4 - 2.2 | Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |
| Sulfuric acid | (CAS No) 7664-93-9 | Used for pH adjustment | 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 advice (show the label where possible).

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

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.

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.

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: Causes serious eye irritation.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

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. Under fire conditions, hazardous fumes will be present.

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 contact with eyes.

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.

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Emergency Procedures: Ventilate area. 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. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill. If spilled directly onto the ground, remove sufficient soil to ensure material is fully recovered.

6.4. Reference to Other Sections

See Heading 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: If heated to the point of fume generation, zinc fumes may cause metal fume fever. Otherwise, zinc is non-toxic. Do not use metal containers for storage.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapors, mist, and spray. Avoid contact with skin, eyes and clothing.

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). Store away from direct sunlight and incompatible materials.

Incompatible Products: Strong acids, strong bases, strong oxidizers. Do not mix with other drugs.

Storage Area: Store in low humidity.

7.3. Specific End Use(s)

Pharmaceutical.

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), NIOSH (REL), or OSHA (PEL).

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

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

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Environmental Exposure Controls : Do not allow the product to be released into the environment.
Consumer Exposure Controls : Do not eat, drink or smoke during use.
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 - 4.0
Evaporation Rate : No data available
Melting Point : No data available
Freezing Point : $\approx 32\text{ }^{\circ}\text{F}$ ($\approx 0\text{ }^{\circ}\text{C}$)
Boiling Point : $\approx 212\text{ }^{\circ}\text{F}$ ($\approx 100\text{ }^{\circ}\text{C}$)
Flash Point : Not flammable, not combustible
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 : No data available
Specific Gravity : Approximately 1.0
Solubility : Freely soluble
Partition Coefficient: N-Octanol/Water : No data available
Viscosity : No data available

9.2. Other Information

VOC content : 0 %

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: Direct sunlight, high or low temperatures, and incompatible materials.
10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers. Do not mix with other drugs.
10.6. Hazardous Decomposition Products: Thermal decomposition generates: Zinc oxide. Sulfur oxides. Sulfur oxides are toxic.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

| Zinc sulfate heptahydrate (7446-20-0) | |
|---------------------------------------|--|
| LD50 Oral Rat | 1260 mg/kg |
| Sulfuric acid (7664-93-9) | |
| LD50 Oral Rat | 2140 mg/kg |
| LC50 Inhalation Rat | 510 mg/m ³ (Exposure time: 2 h) |

Skin Corrosion/Irritation: Not classified

pH: 2.0 - 4.0

Serious Eye Damage/Irritation: Causes serious eye irritation.

pH: 2.0 - 4.0

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

| Sulfuric acid (7664-93-9) | |
|---------------------------|---|
| IARC group | 1 |

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| | |
|--|---|
| 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: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Harmful to aquatic life with long lasting effects. Harmful to aquatic life.

| | |
|--|--|
| Zinc sulfate heptahydrate (7446-20-0) | |
| EC50 Daphnia 1 | 0.068 ml/l (Exposure time: 48 h - Species: Daphnia magna) |
| EC50 Daphnia 2 | 0.15 - 0.5 (Exposure time: 48 h - Species: Daphnia magna) |
| NOEC chronic fish | <= 0.0749 mg/l (Zinc) |
| 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

| | |
|---|---|
| Zinc Sulfate / Conc. Zinc Sulfate Inj, USP | |
| Persistence and Degradability | May cause long-term adverse effects in the environment. |

12.3. Bioaccumulative Potential

| | |
|--|----------------------|
| Zinc Sulfate / Concentrated Zinc Sulfate Inj, USP | |
| Bioaccumulative Potential | Not established. |
| 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.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology – Waste Materials: Avoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

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

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

| | |
|---|---------------------------------|
| Zinc Sulfate / Concentrated Zinc Sulfate Injection, USP | |
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard |
| Zinc sulfate heptahydrate (7446-20-0) | |
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard |
| Sulfuric acid (7664-93-9) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |
| Listed on the United States SARA Section 302 | |
| Listed on United States SARA Section 313 | |

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| | |
|---|--|
| SARA Section 302 Threshold Planning Quantity (TPQ) | 1000 |
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard Delayed (chronic) health hazard |
| SARA Section 313 - Emission Reporting | 1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size) |

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations

Sulfuric acid (7664-93-9)

U.S. - California - Proposition 65 - Carcinogens List

WARNING: This product contains chemicals known to the State of California to cause cancer.

Sulfuric acid (7664-93-9)

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

| | |
|--------------------------|---|
| Revision Date | : 10/26/2020 |
| Other Information | : 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:

| | |
|---------------------|--|
| Acute Tox. 4 (Oral) | Acute toxicity (oral) Category 4 |
| Aquatic Acute 1 | Hazardous to the aquatic environment - Acute Hazard Category 1 |
| Aquatic Acute 3 | Hazardous to the aquatic environment - Acute Hazard Category 3 |
| Aquatic Chronic 1 | Hazardous to the aquatic environment - Chronic Hazard Category 1 |
| Aquatic Chronic 3 | Hazardous to the aquatic environment - Chronic Hazard Category 3 |
| Carc. 1A | Carcinogenicity Category 1A |
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Eye Irrit. 2A | Serious eye damage/eye irritation Category 2A |
| Skin Corr. 1A | Skin corrosion/irritation Category 1A |
| H302 | Harmful if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H350 | May cause cancer |
| H400 | Very toxic to aquatic life |
| H402 | Harmful to aquatic life |
| H410 | Very toxic to aquatic life with long lasting effects |
| H412 | Harmful to aquatic life with long lasting effects |

Refer to 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 American Regent, 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 American Regent has been advised of the possibility of such damages. SDS US (GHS HazCom)