SAFETY DATA SHEET

Zinc Sulfate Injection USP, 25 mg/5 mL (5 mg/mL) and 30 mg/10 mL (3mg/mL)

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Name: Zinc Sulfate Injection USP, 25 mg/5 mL (5 mg/mL) and 30 mg/10 mL (3 mg/mL)

Product Form: Solution

1.2. Intended Use of the Product

Use of the substance/mixture: Zinc sulfate injection is indicated in adult and pediatric patients as a source of zinc for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated

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

Manufactured for

Somerset Therapeutics, LLC. Somerset, NJ 08873

1.4. Emergency Telephone Number

Customer Care: 1-800-417-9175

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) :

GHS 07

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 undilutedby 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

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 USP heptahydrate Equivalent to elemental Zinc	(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 NF	(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 breathingdifficulty 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 andeasy 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 bepresent.

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.

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 toensure 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 orsmoking 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 incompatiblematerials.

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/m³)	0.2 mg/m³ (thoracic fraction)
USA ACGIH	ACGIH chemical category	Suspected Human Carcinogen contained in strong inorganic acid mists
USA NIOSH	NIOSH REL (TWA) (mg/m³)	1 mg/m³
USA IDLH	US IDLH (mg/m³)	15 mg/m³
USA OSHA	OSHA PEL (TWA) (mg/m³)	1 mg/m³

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.

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 : ≈ 32 °F (≈0 °C)

Boiling Point	: ≈ 212 °F (≈100 °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/m³ (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
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.
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) inventoryListed on the United States SARA Section 302 Listed on United States SARA Section 313	
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 OTEHER INFORMAION INCLUDING DATE OF PREPARATION OR LAST REVISION

Prepared Date : 18/07/2024
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR1910.1200.

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

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END OF SAFETY DATA SHEET