

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Selenious Acid Injection, USP

Product Code: 0517-6560-25; 0517-6560-05

1.2. Intended Use of the Product

Use of the Substance/Mixture: Selenious Acid Injection, USP is a trace element indicated in adult and pediatric patients as a source of selenium for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

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

Company

American Regent, Inc.

5 Ramsey Road

Shirley NY, 11967

1-800-645-1706

<http://www.americanreagent.com/>

1.4. Emergency Telephone Number

Emergency Number : 1-800-424-9300 (CHEMTREC)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Skin Corr. 1A H314

Eye Dam. 1 H318

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



Signal Word (GHS-US) :

Danger

Hazard Statements (GHS-US) :

H314 - Causes severe skin burns and eye damage.

H318 - Causes serious eye damage.

Precautionary Statements (GHS-US) :

P260 - Do not breathe vapors, mist, or spray.

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

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

P301+P330+P331 - If swallowed: rinse mouth. Do NOT induce vomiting.

P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.

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

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

P310 - Immediately call a poison center or doctor.

P363 - Wash contaminated clothing before reuse.

P405 - Store locked up.

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

2.3. Other Hazards

Exposure may aggravate individuals with pre-existing skin, kidney, liver, and pulmonary disorders. Exposure may aggravate pre-existing eye, skin, or respiratory conditions. Selenious Acid Injection should not be given undiluted by direct injection into a peripheral vein because of the potential for infusion phlebitis. Repeated exposure to this product may result in hair loss, weakened nails, dermatitis, dental defects, gastrointestinal disorders, nervousness, mental depression, metallic taste, vomiting, fulminating peripheral vascular collapse, internal vascular congestion, diffusely hemorrhagic, congested and edematous lungs, red color gastric mucosa, coma, and death. Refer to patient insert for more information.

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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 | Synonyms | Product Identifier | % | GHS US classification |
|----------------|---|---------------------|--------------------|---|
| Water | AQUA / Aqua | (CAS-No.) 7732-18-5 | 99.99 | Not classified |
| Selenious acid | Selenious acid (H ₂ SeO ₃) / Selenous acid | (CAS-No.) 7783-00-8 | 0.01 | Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Inhalation), H331 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |
| Nitric acid | Hydrogen sulfide / Nitric acid, red fuming | (CAS-No.) 7697-37-2 | *Used to adjust pH | Ox. Liq. 3, H272 Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 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: Remove to fresh air and keep at rest in a position comfortable for breathing. Immediately call a poison center or doctor/physician.

First-aid Measures After Skin Contact: Immediately remove contaminated clothing. Immediately flush skin with plenty of water for at least 60 minutes. Get immediate medical advice/attention.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 60 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. Immediately call a POISON CENTER or doctor/physician.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Causes severe skin burns and eye damage. When handling in workplace settings, in quantities that are most likely above the therapeutic dose, this product may be harmful if absorbed through the eyes, skin, or respiratory tract.

Symptoms/Injuries After Inhalation: Corrosive to the respiratory tract.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Redness, pain, swelling, itching, burning, tearing, and blurred vision. Causes permanent damage to the cornea, iris, or conjunctiva.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects. May cause burns or irritation of the linings of the mouth, throat, and gastrointestinal tract.

Chronic Symptoms: Exposure to this product may result in nervousness, depression, hair loss, weakened nails, and dental defects. Ingestion of product may result in gastrointestinal disorders and vomiting. A garlic odor and taste may be observed as well following exposure.

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: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

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 flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

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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.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe vapor, mist or spray. Do not get in eyes, on skin, or on clothing.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

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. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. As an immediate precautionary measure, isolate spill or leak area in all directions.

Methods for Cleaning Up: Wipe working surfaces to dryness, and then wash with soap and water. Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill. Cautiously neutralize spilled liquid.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mist, spray. Do not mix with other drugs. Practice good housekeeping - spillage can be slippery on smooth surface either wet or dry. May release corrosive vapors.

Precautions for Safe Handling: Do not breathe mist, spray, vapors. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not get in eyes, on skin, or on clothing. Handle empty containers with care because they may still present a hazard.

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: Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store in original container or corrosive resistant and/or lined container. Store locked up/in a secure area.

Incompatible Materials: Strong oxidizers. Strong bases. Ammonia.

Storage Temperature: 20 - 25 °C (68 °F to 77 °F)

7.3. Specific End Use(s)

Selenious Acid Injection, USP is a trace element indicated in adult and pediatric patients as a source of selenium for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

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).

| Nitric acid (7697-37-2) | | |
|-------------------------|---------------------------------------|----------------------|
| USA ACGIH | ACGIH TWA (ppm) | 2 ppm |
| USA ACGIH | ACGIH STEL (ppm) | 4 ppm |
| USA NIOSH | NIOSH REL (TWA) (mg/m ³) | 5 mg/m ³ |
| USA NIOSH | NIOSH REL (TWA) (ppm) | 2 ppm |
| USA NIOSH | NIOSH REL (STEL) (mg/m ³) | 10 mg/m ³ |
| USA NIOSH | NIOSH REL (STEL) (ppm) | 4 ppm |

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| | | |
|----------|-------------------------------------|---------------------|
| USA IDLH | US IDLH (ppm) | 25 ppm |
| USA OSHA | OSHA PEL (TWA) (mg/m ³) | 5 mg/m ³ |
| USA OSHA | OSHA PEL (TWA) (ppm) | 2 ppm |

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. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Personal Protective Equipment

: Protective goggles. Gloves. Protective clothing. Insufficient ventilation: wear respiratory protection. Face shield.



Materials for Protective Clothing

: Chemically resistant materials and fabrics. Corrosion-proof clothing.

Hand Protection

: Wear chemically resistant protective gloves. Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles and face shield.

Skin and Body Protection

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

Respiratory Protection

: In case of inadequate ventilation wear 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.

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 solution |
| Odor | : Odorless |
| Odor Threshold | : No data available |
| pH | : 1.8 - 2.4 |
| Evaporation Rate | : No data available |
| Melting Point | : No data available |
| Freezing Point | : 0 °C (32 °F) Approximately |
| Boiling Point | : 100 °C (212 °F) Approximately |
| Flash Point | : No data available |
| Auto-ignition Temperature | : No data available |
| Decomposition Temperature | : No data available |
| Flammability (solid, gas) | : Not applicable |
| Vapor Pressure | : No data available |
| Relative Vapor Density at 20°C | : No data available |
| Relative Density | : No data available |
| Specific Gravity | : 1 Approximately |
| Solubility | : Water: Freely soluble in water |
| Partition Coefficient: N-Octanol/Water | : No data available |
| Viscosity | : No data available |

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:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong oxidizers. Strong bases. Ammonia.

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10.6. Hazardous Decomposition Products: Thermal decomposition generates: Carbon oxides (CO, CO₂). Selenium and its oxides. Nitrogen oxides. Toxic fumes. Corrosive vapors.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

| Selenious acid (7783-00-8) | |
|----------------------------|--------------------------|
| ATE (Oral) | 100.00 mg/kg body weight |
| ATE (Gases) | 700.00 ppmV/4h |
| ATE (Vapors) | 3.00 mg/l/4h |
| ATE (Dust/Mist) | 0.50 mg/l/4h |
| Nitric acid (7697-37-2) | |
| LC50 Inhalation Rat | 0.126 mg/l/4h |
| LC50 Inhalation Rat | 2500 ppm/1h |
| LC50 Inhalation Rat | 130 mg/l/4h |
| ATE (Gases) | 1,250.00 ppmV/4h |

Skin Corrosion/Irritation: Causes severe skin burns and eye damage.

pH: 1.8 - 2.4

Serious Eye Damage/Irritation: Causes serious eye damage.

pH: 1.8 - 2.4

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

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: Corrosive to the respiratory tract.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Redness, pain, swelling, itching, burning, tearing, and blurred vision. Causes permanent damage to the cornea, iris, or conjunctiva.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects. May cause burns or irritation of the linings of the mouth, throat, and gastrointestinal tract.

Chronic Symptoms: Exposure to this product may result in nervousness, depression, hair loss, weakened nails, and dental defects. Ingestion of product may result in gastrointestinal disorders and vomiting. A garlic odor and taste may be observed as well following exposure.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

| Nitric acid (7697-37-2) | |
|-------------------------|---------|
| LC50 Fish 1 | 72 mg/l |

12.2. Persistence and Degradability

| Selenious Acid Injection, USP | |
|-------------------------------|------------------|
| Persistence and Degradability | Not established. |

12.3. Bioaccumulative Potential

| Selenious Acid Injection, USP | |
|-------------------------------|------------------|
| Bioaccumulative Potential | Not established. |

| Nitric acid (7697-37-2) | |
|-------------------------|-----------------|
| Log Pow | -2.3 (at 25 °C) |

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

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SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Sewage Disposal Recommendations: Do not empty into drains; dispose of this material and its container in a safe way.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations. 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.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

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

| | |
|--|---|
| Selenious Acid Injection, USP | |
| SARA Section 311/312 Hazard Classes | Immediate (acute) health hazard Health hazard - Serious eye damage or eye irritation Health hazard - Skin corrosion or Irritation |
| Selenious acid (7783-00-8) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 | |
| CERCLA RQ | 10 lb |
| SARA Section 302 Threshold Planning Quantity (TPQ) | 1000 - 10000 lb |
| Nitric acid (7697-37-2) | |
| 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 | |
| CERCLA RQ | 1000 lb |
| SARA Section 302 Threshold Planning Quantity (TPQ) | 1000 lb |
| SARA Section 313 - Emission Reporting | 1 % |
| Water (7732-18-5) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |

15.2. US State Regulations

| |
|--|
| Selenious acid (7783-00-8) |
| 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 |
| Nitric acid (7697-37-2) |
| 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

Date of Preparation or Latest Revision : 08/21/2019

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. 3 (Inhalation) | Acute toxicity (inhalation) Category 3 |
| Acute Tox. 3 (Oral) | Acute toxicity (oral) Category 3 |

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| | |
|-------------------|---|
| 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 |
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Met. Corr. 1 | Corrosive to metals Category 1 |
| Ox. Liq. 3 | Oxidizing liquids Category 3 |
| Skin Corr. 1A | Skin corrosion/irritation Category 1A |
| STOT RE 2 | Specific target organ toxicity (repeated exposure) Category 2 |
| H272 | May intensify fire; oxidizer |
| H290 | May be corrosive to metals |
| H301 | Toxic if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H318 | Causes serious eye damage |
| H331 | Toxic if inhaled |
| H373 | May cause damage to organs through prolonged or repeated exposure |
| H400 | Very toxic to aquatic life |
| H402 | Harmful to aquatic life |
| H410 | Very toxic to aquatic life with long lasting effects |

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)