

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Selenium Injection (as Selenious Acid)

Product Code: NDIC-0517-6510-25

1.2. Intended Use of the Product

Use of the substance/mixture: Indicated for use as a supplement to intravenous solutions given for total parental nutrition (TPN). Administration of selenium in TPN solutions helps to maintain plasma selenium levels and to prevent depletion of endogenous stores and subsequent deficiency symptoms.

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

Company

American Regent, Inc.

5 Ramsey Road

P.O. Box 9001

Shirley, NY

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)

Skin Corr. 1A H314

Eye Dam. 1 H318

Full text of H-phrases: 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.

P321 - Specific treatment (see section 4 on this SDS).

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. Selenium Injection should not be given undiluted by direct injection into a peripheral vein because of the potential for infusion phlebitis. Exposure to this

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product may result in nervousness, depression, hair loss, weakened nails, and dental defects. A garlic odor and taste may be observed as well following exposure. Refer to patient insert for more information.

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	(CAS No) 7732-18-5	99.993	Not classified
Selenious acid	(CAS No) 7783-00-8	0.007	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Inhalation), H331 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Nitric acid	(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

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). In the event of accidental injection, immediately call a poison center or seek medical advice.

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Seek medical attention.

First-aid Measures After Skin Contact: Remove contaminated clothing. Immediately flush skin with plenty of water for at least 60 minutes. Seek medical attention immediately if irritation develops or persists.

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. Exposure to this product may result in nervousness, depression, hair loss, weakened nails, and dental defects. A garlic odor and taste may be observed as well following exposure. Please refer to the package insert for more detailed information.

Symptoms/Injuries After Inhalation: Contact may cause immediate severe irritation progressing quickly to chemical burns.

Symptoms/Injuries After Skin Contact: May be absorbed through the skin in harmful amounts. Causes severe skin burns. Symptoms may include: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Causes serious eye damage. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects. Ingestion of product may result in gastrointestinal disorders and vomiting.

Chronic Symptoms: May impact eyes, pulmonary and gastrointestinal tract, skin, kidneys, and liver. Repeated Exposure may result in contact dermatitis.

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

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: A heavy water stream may spread burning liquid. CAUTION: Carbon dioxide is an asphyxiant. Lack of oxygen can be fatal.

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5.2. Special Hazards Arising From the Substance or Mixture

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Firefighting Instructions: Exercise caution when fighting any chemical fire. Do not breathe fumes from fires or vapors from decomposition. Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Firefighters must use full bunker gear including NIOSH-approved positive-pressure self-contained breathing apparatus to protect against potential hazardous combustion and decomposition products.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid all unnecessary exposure. Do not breathe vapour or mist.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE). Refer to section 8.2.

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection. For further information refer to section 8: Exposure Controls/Personal Protection.

Emergency Procedures: Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection. For further information refer to Section 13.

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.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

Incompatible Products: Strong bases. Strong oxidizers. Ammonia.

7.3. Specific End Use(s)

Indicated for use as a supplement to intravenous solutions given for total parental nutrition (TPN). Administration of selenium in TPN solutions helps to maintain plasma selenium levels and to prevent depletion of endogenous stores and subsequent deficiency symptoms.

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).

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
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

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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

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



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

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.

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

: Approximately 0 °C (32 °F)

Boiling Point

: Approximately 100 °C (212 °F)

Flash Point

: Not applicable

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

Solubility

: Freely soluble in water

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. Extremely high or low temperatures. Humidity. Incompatible materials.

10.5. Incompatible Materials: Strong oxidizers. Strong bases. Ammonia.

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

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

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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	67 ppm/4h
ATE (Dust/Mist)	130.00 mg/l/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: Contact may cause immediate severe irritation progressing quickly to chemical burns.

Symptoms/Injuries After Skin Contact: May be absorbed through the skin in harmful amounts. Causes severe skin burns.

Symptoms may include: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Causes serious eye damage. Symptoms may include: Redness, pain, swelling, itching, burning, tearing, and blurred vision.

Symptoms/Injuries After Ingestion: Potent pharmaceutical- ingestion may be harmful or have adverse effects. Ingestion of product may result in gastrointestinal disorders and vomiting.

Chronic Symptoms: May impact eyes, pulmonary and gastrointestinal tract, skin, kidneys, and liver. Repeated Exposure may result in contact dermatitis.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity No additional information available

12.2. Persistence and Degradability

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Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Selenium Injection (as Selenious Acid)	
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.

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.

Additional Information: Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

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

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SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
Selenious acid (7783-00-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
SARA Section 302 Threshold Planning Quantity (TPQ)	≤ 10000
Nitric acid (7697-37-2)	
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	
SARA Section 302 Threshold Planning Quantity (TPQ)	1000
SARA Section 313 - Emission Reporting	1.0 %
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

Revision Date	: 01/10/2019
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
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
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
H410	Very toxic to aquatic life with long lasting effects

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

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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, Inc., 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, Inc. has been advised of the possibility of such damages.

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