

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Atropine Sulfate Injection, USP

Product Code: 0517-0401-25; 0517-1010-25; 0517-1004-01; 0517-1004-25; 0517-1001-01; 0517-1001-25

1.2. Intended Use of the Product

Use of the substance/mixture: 1. In the treatment of parkinsonism. Rigidity and tremor relieved by the apparently selective depressant action. 2. In the gastrointestinal tract to relieve pylorospasm, hypertonicity of the small intestine and the hypermotility of the colon. 3. To relieve hypertonicity of the uterine muscle. 4. To relax the spasm of biliary and uretered colic and bronchial spasm. 5. To diminish the tone of the detrusor muscle of the urinary bladder in the treatment of urinary tract disorders. 6. To control the crying and laughing episodes in patients with brain lesions. 7. In cases of closed head injuries which cause acetylcholine to be released or to be present in cerebrospinal fluid which in turn causes abnormal EEG patterns, stupor and neurological signs. 8. In the management of peptic ulcer. 9. In anesthesia to control excessive salivation and bronchial secretions. 10. To control rhinorrhea of acute rhinitis or hay fever. 11. As an antidote for pilocarpine, physostigmine, isoflurophate, choline esters, certain species of Aminata and in cases of anticholinesterase insecticide poisoning. 12. In poisoning by the organic phosphate cholinesterase inhibitors found in certain insecticides and by chemical warfare "nerve gases", large doses of atropine relieve the muscarine-like symptoms and some of the central-nervous-system manifestations. Adults suspected of contact with organic phosphorus insecticides of the parathion type should be given atropine sulfate, 0.8 mg, intramuscularly. If an atropine effect is not apparent within thirty minutes or if definite symptoms of the poisoning occur (nausea, vomiting, diarrhea, pupillary constriction, pulmonary edema, fasciculations of eyelids and tongue, jerky ocular movements, and excessive sweating, salivation, and bronchial secretion), atropine sulfate, 2 mg, should be given intramuscularly at hourly intervals until signs of atropinization are observed. Up to two or three times this dose (4 to 6 mg) may be required in severe cases. Removing contaminated clothing, washing the skin, and commencing artificial respiration and supportive therapy are also indicated.

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)

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards Exposure can lead to rash, blurred vision, irregular pulse, tachycardia, lowered blood pressure and respiratory depression. 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 for injection	(CAS No) 7732-18-5	96.5 - 97	Not classified
Sodium chloride	(CAS No) 7647-14-5	0.9	Not classified
Atropine Sulfate	(CAS No) 55-48-1	0.04 - 0.1	Acute Tox. 4 (Oral), H302 Acute Tox. 2 (Inhalation: dust, mist), H330

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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
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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. Flush with copious quantities of water for 15 minutes. Seek medical advice.

First-aid Measures After Eye Contact: Immediately flush eyes thoroughly with water for at least 20 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting.

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

Symptoms/Injuries: Not expected to present a significant hazard under anticipated conditions of normal use. Please refer to the package insert for more detailed information.

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.

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. 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.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

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.

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Storage Conditions: Store in original container. Store in a dry, cool and well-ventilated place.

Incompatible Products: Strong bases. Strong oxidizers.

Storage Temperature: 20 - 25 °C (68 - 77 °F) Excursions permitted to 15 - 30 °C (59 - 86 °F)

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 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. Safety glasses.



Hand Protection : Wear chemically resistant protective gloves.

Eye Protection : Chemical goggles or safety glasses.

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	: 3 - 6.5
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: ≈ 100 °C (212 °F)
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
Specific Gravity	: ≈ 1.0
Solubility	: 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.

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10.5. Incompatible Materials: Strong oxidizers. Strong bases.

10.6. Hazardous Decomposition Products: Thermal decomposition generates: Carbon oxides (CO, CO₂), Halogenated compounds, Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Water (7732-18-5)	
LD50 Oral Rat	> 90000 mg/kg
Atropine Sulfate (55-48-1)	
LD50 Oral Rat	600 mg/kg
ATE (Dust/Mist)	0.05 mg/l/4h
Sodium chloride (7647-14-5)	
LD50 Oral Rat	3 g/kg
LC50 Inhalation Rat	> 42 g/m ³ (Exposure time: 1 h)
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: 3 - 4.5)

Serious Eye Damage/Irritation: Not classified (pH: 3 - 4.5)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

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Additional information	There is sufficient evidence that occupational exposure to strong inorganic acid mists containing sulfuric acid is carcinogenic.
Sulfuric acid (7664-93-9)	
IARC group	1

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 - 6080 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
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

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Bioaccumulative Potential	Not established.
Sodium chloride (7647-14-5)	
BCF fish 1	(no bioaccumulation)
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.

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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.

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

Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Atropine Sulfate (55-48-1)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium chloride (7647-14-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
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	
SARA Section 302 Threshold Planning Quantity (TPQ)	1000
SARA Section 313 - Emission Reporting	1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)

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 : 01/21/2021

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. 2 (Inhalation: dust, mist)	Acute toxicity (inhalation: dust, mist) Category 2
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Carc. 1A	Carcinogenicity Category 1A
Eye Dam. 1	Serious eye damage/eye irritation Category 1
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
H330	Fatal if inhaled
H350	May cause cancer
H402	Harmful to aquatic life

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

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