SECTION 1: IDENTIFICATION

1.1. Product Identifier
Product Form: Solution
Product Name: Atropine Sulfate Injection, USP
Product Code: NDIC-0517-0401-25; NDIC-0517-1010-25

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 ureteral 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, isofluorophate, choline esters, certain species of Aminata and in cases of anticholinesterase insecticide poisoning. 12. In poisoning by the organic phosphorus 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

Distributor: American Regent, Inc.
One Luitpold Drive
PO Box 9001
Shirley, NY 11967
1-800-645-1706

Manufacturer: Luitpold Pharmaceuticals, Inc.
P.O. Box 9001
Shirley, NY 11967
1-800-645-1706
www.luitpold.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 may result in rash, blurred vision, irregular pulse, tachycardia, lowered blood pressure and respiratory depression. Refer to prescribing information 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. Solution

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier (CAS No)</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water for Injection</td>
<td>(CAS No) 7732-18-5</td>
<td>99.0 to 99.06</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>(CAS No) 7647-14-5</td>
<td>0.9</td>
<td>Not classified</td>
</tr>
<tr>
<td>Atropine Sulfate</td>
<td>(CAS No) 55-48-1</td>
<td>0.04 - 0.1</td>
<td>Acute Tox. 4 (Oral), H302</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 2 (Inhalation:dust,mist), H330</td>
</tr>
</tbody>
</table>
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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 |

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 attention. (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical attention.
First-aid Measures After Inhalation: 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 attention.
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.

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 prescribing information for more detailed information.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed
If you feel unwell, seek medical attention (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 vapor or mist.

6.1.1. For Non-emergency Personnel
Protective Equipment: Use appropriate personal protection equipment (PPE). Refer to section 8.2.

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.

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

Incompatible Products: Strong bases. Strong oxidizers.


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).

<table>
<thead>
<tr>
<th>Chemical</th>
<th>USA ACGIH</th>
<th>USA NIOSH</th>
<th>USA IDLH</th>
<th>USA OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric Acid</td>
<td>ACGIH TWA (mg/m³)</td>
<td>NIOSH REL (TWA) (mg/m³)</td>
<td>US IDLH (mg/m³)</td>
<td>OSHA PEL (TWA) (mg/m³)</td>
</tr>
<tr>
<td>(7664-93-9)</td>
<td>0.2 mg/m³ (thoracic fraction)</td>
<td>1 mg/m³</td>
<td>15 mg/m³</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>ACGIH Ceiling (mg/m³)</td>
<td>NIOSH REL (ceiling) (mg/m³)</td>
<td>US IDLH (mg/m³)</td>
<td>OSHA PEL (TWA) (mg/m³)</td>
</tr>
<tr>
<td>(1310-73-2)</td>
<td>2 mg/m³</td>
<td>2 mg/m³</td>
<td>10 mg/m³</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

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: 3.0 - 6.5
Evaporation Rate: No data available
Melting Point: No data available
Freezing Point: = 0 °C (32 °F)
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
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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. High or low temperatures.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects
Acute Toxicity: Not classified
Water for Injection (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/m³ (Exposure time: 1 h)
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: 3.0 - 6.5)
Serious Eye Damage/Irritation: Not classified (pH: 3.0 - 6.5)
Respiratory or Skin Sensitization: Not classified
Germ Cell Mutagenicity: Not classified
Carcinogenicity: Not classified
Atropine Sulfate Injection, USP
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])
Sodium Hydroxide (1310-73-2)
LC50 Fish 1 45.4 mg/l (Exposure time: 96 h – Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1 40 mg/l
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<table>
<thead>
<tr>
<th>Sulfuric Acid (7664-93-9)</th>
<th></th>
</tr>
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<tbody>
<tr>
<td>LC50 Fish 1</td>
<td>500 mg/l (Exposure time: 96 h - Species: Brachydanio rerio [static])</td>
</tr>
<tr>
<td>LC 50 Fish 2</td>
<td>42 mg/l (Exposure time: 96 h - Species: Gambusia affinis [static])</td>
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</table>

12.2. Persistence and Degradability
Not established

12.3. Bioaccumulative Potential

<table>
<thead>
<tr>
<th>Atropine Sulfate Injection, USP</th>
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</thead>
<tbody>
<tr>
<td>Bioaccumulative Potential</td>
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<td>BCF fish 1</td>
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<tbody>
<tr>
<td>BCF fish 1</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>Water for Injection (7732-18-5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Listed on the United States TSCA (Toxic Substances Control Act) inventory</td>
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<th>Sodium Hydroxide (1310-73-2)</th>
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<tr>
<td>Listed on the United States TSCA (Toxic Substances Control Act) inventory</td>
</tr>
<tr>
<td>Listed on United States SARA Section 302</td>
</tr>
<tr>
<td>Listed on United States SARA Section 313</td>
</tr>
</tbody>
</table>

| SARA Section 302 Threshold Planning Quantity (TPQ) |
|---------------------------------|---|
| 1000                            |

<table>
<thead>
<tr>
<th>SARA Section 313 - Emission Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)</td>
</tr>
</tbody>
</table>

15.2 US State Regulations

<table>
<thead>
<tr>
<th>Sulfuric Acid (7664-93-9)</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. - California - Proposition 65 - Carcinogens List</td>
</tr>
<tr>
<td>WARNING: This product contains chemicals known to the State of California to cause cancer.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sodium Hydroxide (1310-73-2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. - Massachusetts - Right To Know List</td>
</tr>
<tr>
<td>U.S. - New Jersey - Right to Know Hazardous Substance List</td>
</tr>
<tr>
<td>U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List</td>
</tr>
<tr>
<td>U.S. - Pennsylvania - RTK (Right to Know) List</td>
</tr>
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SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date: 03/03/2015
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:

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td>Acute Tox. 2 (Inhalation:dust,mist)</td>
<td>Acute toxicity (inhalation:dust,mist) Category 2</td>
</tr>
<tr>
<td>Acute Tox. 4 (Oral)</td>
<td>Acute toxicity (oral) Category 4</td>
</tr>
<tr>
<td>Aquatic Acute 3</td>
<td>Hazardous to the aquatic environment - Acute Hazard Category 3</td>
</tr>
<tr>
<td>Carc. 1A</td>
<td>Carcinogenicity Category 1A</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>Serious eye damage/eye irritation Category 1</td>
</tr>
<tr>
<td>Skin Corr. 1A</td>
<td>Skin corrosion/irritation Category 1A</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H330</td>
<td>Fatal if inhaled</td>
</tr>
<tr>
<td>H350</td>
<td>May cause cancer</td>
</tr>
<tr>
<td>H402</td>
<td>Harmful to aquatic life</td>
</tr>
</tbody>
</table>

Refer to Luitpold/American Regent prescribing information for further information at: http://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 Luitpold, 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 Luitpold has been advised of the possibility of such damages.

SDS US (GHS HazCom)