MATERIAL SAFETY DATA SHEET

Product Name: Atropine Sulfate Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Atropine Sulfate Injection

Synonyms
1αH, 5αH-Tropan-3-α-ol (±)-tropate (ester), sulfate (2:1) (salt) monohydrate,

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Atropine Sulfate Monohydrate

Chemical Formula
(C_{17}H_{23}NO_3)_2•H_2SO_4•H_2O

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride. Hydrochloric acid and/or sodium hydroxide are added to adjust the pH.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atropine Sulfate Monohydrate</td>
<td>0.01</td>
<td>73791-47-6</td>
<td>CK2455000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atropine Sulfate Monohydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Atropine Sulfate Injection is a solution containing atropine sulfate, an anticholinergic drug that blocks the effects of acetylcholine in the body resulting is effects on many organ systems including the eyes, gastrointestinal tract, heart, lung and central nervous system. Clinically, atropine sulfate is used to treat a variety of GI disorders, to reduce salivation and secretions during surgery, and to dilate pupils. In the workplace, this material should be considered a potential eye and respiratory irritant. Based on clinical use, possible target organs include the eyes, skin, gastrointestinal system, respiratory system, central nervous system, and cardiovascular system.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
No signs or symptoms from occupational exposure are known. In clinical use, atropine can cause suppressed salivation, dilated pupils, blurred vision, hot/dry sensation, disorientation, increased heart rate, constipation, nausea, urinary retention and hesitancy, palpitation, dizziness,
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drowsiness, decreased bronchi secretion, photophobia, dry mouth, fever, glaucoma, difficulty breathing, flushing, rashes and vomiting.

Medical Conditions
Pre-existing sensitivity to atropine and belladonna alkaloids; pre-existing glaucoma, tachycardia, gastrointestinal or biliary tract obstruction. Prostate hypertrophy.

### 4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
</tbody>
</table>

### 5. FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Feature</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>None anticipated for this aqueous product.</td>
</tr>
<tr>
<td>Fire &amp; Explosion Hazard</td>
<td>None anticipated for this aqueous product.</td>
</tr>
<tr>
<td>Extinguishing media</td>
<td>As with any fire, use extinguishing media appropriate for primary cause of fire.</td>
</tr>
<tr>
<td>Special Fire Fighting</td>
<td>No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.</td>
</tr>
<tr>
<td>Procedures</td>
<td>No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.</td>
</tr>
</tbody>
</table>

### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Feature</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spill Cleanup and Disposal</td>
<td>Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.</td>
</tr>
</tbody>
</table>

### 7. HANDLING AND STORAGE

<table>
<thead>
<tr>
<th>Feature</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling</td>
<td>No special handling required under conditions of normal product use.</td>
</tr>
<tr>
<td>Storage</td>
<td>No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.</td>
</tr>
<tr>
<td>Special Precautions</td>
<td>No special precautions required for hazard control.</td>
</tr>
</tbody>
</table>
Product Name: Atropine Sulfate Injection

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Exposure Guidelines</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component</td>
<td>Type</td>
</tr>
<tr>
<td>Atropine Sulfate Monohydrate</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**Respiratory protection**
Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**
If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**
Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**
Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

- **Appearance/Physical State**: Liquid
- **Color**: Clear
- **Odor**: NA
- **Odor Threshold**: NA
- **pH**: 4.2 (3.0 to 6.5)
- **Melting point/Freezing point**: NA
- **Initial Boiling Point/Boiling Point Range**: NA
- **Evaporation Rate**: NA
- **Flammability (solid, gas)**: NA
- **Upper/Lower Flammability or Explosive Limits**: NA
- **Vapor Pressure**: NA
- **Vapor Density**: NA
- **Specific Gravity**: NA
- **Solubility**: NA
- **Partition coefficient: n-octanol/water**: NA
- **Auto-ignition temperature**: NA
- **Decomposition temperature**: NA
10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Not determined.

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and sulfur oxides (SOx).

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atropine Sulfate Monohydrate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>56</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Atropine Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>37,73</td>
<td>mg/k</td>
<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>31</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td>70</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>Atropine Sulfate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>500</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>468</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce stinging followed by blurred vision and sensitivity to light.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product.

Reproductive Effects
Animal reproduction studies have not been conducted with atropine. Studies have not been performed to determine its potential to adversely affect fertility.

Mutagenicity
Studies have not been performed to evaluate the mutagenic potential of atropine.

Carcinogenicity
Studies have not been performed to evaluate the carcinogenic potential of atropine.
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Target Organ Effects
Based on clinical use, possible target organs include the eyes, skin, gastrointestinal system, respiratory system, central nervous system, and cardiovascular system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product.

Persistence/Biodegradability
Not determined for product.

Bioaccumulation
Not determined for product.

Mobility in Soil
Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:
Not regulated

IMDG STATUS:
Not regulated

ICAO/IATA STATUS:
Not regulated

Transport Comments:
None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atropine Sulfate Monohydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</table>

RCRA Status
Not Listed

U.S. OSHA Classification
Target Organ Toxin

GHS Classification
Possible Irritant

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:
Product Name: Atropine Sulfate Injection

Hazard Class: Not Applicable
Hazard Category: Not Applicable
Signal Word: Not Applicable
Symbol: Not Applicable

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell.

EU Classification*
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Atropine Sulfate Monohydrate.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases: S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.
16. OTHER INFORMATION:

Notes:
ACGIH TLV    American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS          Chemical Abstracts Service Number
CERCLA       US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT          US Department of Transportation Regulations
EEL          Employee Exposure Limit
IATA         International Air Transport Association
LD50         Dosage producing 50% mortality
NA           Not applicable/Not available
NE           Not established
NIOSH        National Institute for Occupational Safety and Health
OSHA PEL     US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65      California Proposition 65
RCRA         US EPA, Resource Conservation and Recovery Act
RTECS        Registry of Toxic Effects of Chemical Substances
SARA         Superfund Amendments and Reauthorization Act
STEL         15-minute Short Term Exposure Limit
TSCA         Toxic Substance Control Act
TWA          8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared:  09/01/2011
Obsolete Date:  10/21/2008

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