

MATERIAL SAFETY DATA SHEET

Product Name: Atropine Sulfate Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira Inc.
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Lake Forest, Illinois USA
60045

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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 $(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4 \cdot H_2O$

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.

| Component | Approximate Percent by Weight | CAS Number | RTECS Number |
|------------------------------|-------------------------------|------------|--------------|
| Atropine Sulfate Monohydrate | 0.01 | 73791-47-6 | CK2455000 |

3. HAZARD INFORMATION

Carcinogen List

| Substance | IARC | NTP | OSHA |
|------------------------------|------------|------------|------------|
| Atropine Sulfate Monohydrate | Not Listed | Not Listed | Not Listed |

Emergency Overview Atropine Sulfate Injection is a solution containing atropine sulfate, an anticholinergic drug that blocks the effects of acetylcholine in the body resulting in 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,
Aggravated by Exposure tachycardia, gastrointestinal or biliary tract obstruction. Prostate hypertrophy.

4. FIRST AID MEASURES

| | |
|---------------------|---|
| Eye contact | 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. |
| Skin contact | 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. |
| Inhalation | Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. |
| Ingestion | Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. |

5. FIRE FIGHTING MEASURES

| | |
|---|--|
| Flammability | None anticipated for this aqueous product. |
| Fire & Explosion Hazard | None anticipated for this aqueous product. |
| Extinguishing media | As with any fire, use extinguishing media appropriate for primary cause of fire. |
| Special Fire Fighting Procedures | No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus. |

6. ACCIDENTAL RELEASE MEASURES

| | |
|-----------------------------------|--|
| Spill Cleanup and Disposal | 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. |
|-----------------------------------|--|

7. HANDLING AND STORAGE

| | |
|----------------------------|---|
| Handling | No special handling required under conditions of normal product use. |
| Storage | 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. |
| Special Precautions | No special precautions required for hazard control. |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

| Component | Type | Exposure limits | | | |
|------------------------------|------|-----------------|-----|-------|---------|
| | | mg/m3 | ppm | µg/m3 | Note |
| Atropine Sulfate Monohydrate | | N/A | N/A | 4 | 8hr TWA |

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:

| Ingredient(s) | Percent | Test Type | Route of Administration | Value | Units | Species |
|------------------------------|----------------|------------------|--------------------------------|--------------|--------------|----------------|
| Atropine Sulfate Monohydrate | 100 | LD50 | Intravenous | 56 | mg/kg | Mouse |
| Atropine Sulfate | 100 | LD50 | Intravenous | 37,73 | mg/k | Rat |
| | | | | 31 | mg/kg | Mouse |
| | | | | 70 | mg/kg | Rabbit |
| | | | | 60 | mg/kg | Dog |
| Atropine Sulfate | 100 | LD50 | Oral | 500 | mg/kg | Rat |
| | | | | 468 | mg/kg | Mouse |

| | |
|--|---|
| 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

| Substance | TSCA Status | CERCLA Status | SARA 302 Status | SARA 313 Status | PROP 65 Status |
|------------------------------|-------------|---------------|-----------------|-----------------|----------------|
| Atropine Sulfate Monohydrate | Not Listed | Not Listed | Not Listed | Not Listed | Not Listed |

RCRA Status Not Listed
U.S. OSHA Classification Target Organ Toxin
Possible Irritant

GHS Classification *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:

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| | |
|-------------------------|--|
| Hazard Class | Not Applicable |
| Hazard Category | Not Applicable |
| Signal Word | Not Applicable |
| Symbol | Not Applicable |
| Prevention | P260 - Do not breathe dust/fume/gas/mist/vapors/spray. |
| Hazard Statement | 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

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