Hospira

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	$(C_{17}H_{23}NO_3)2 \cdot H_2SO_4 \cdot H_2O$
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 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,

drowsiness, decreased bronchi secretion, photophobia, dry mouth, fever, glaucoma, difficulty breathing, flushing, rashes and vomiting.

Medical Conditions Aggravated by Exposure	Pre-existing sensitivity to atropine and belladonna alkaloids; pre-existing glaucoma, 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

	Exposure limits				
Component	Type	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 31 70 60	mg/k mg/kg mg/kg mg/kg	Rat Mouse Rabbit Dog
Atropine Sulfate	100	LD50	Oral	500 468	mg/kg mg/kg	Rat 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.

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:

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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