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INTERNATIONAL MEDICATION SYSTEMS, LIMITED
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AREA CODE (800) 423-4136, (909) 980-9484 (INTERNATIONAL)
FAX (626) 459-5255

MATERIAL SAFETY DATA SHEET

SECTION I. IDENTIFICATION	
Identity/Material Name	Atropine Sulfate Injection, 0.1 mg/ml
Synonyms	1 α H, 5 α H – Tropan-3 α-ol (±) – tropate (ester), sulfate (2:1) (salt) monohydrate
Stock Number	3339
NDC Number	76329-3339-1
Unit Size	1 mg/10mL (in single use prefilled syringes)
Intended Use	Rx Only. Atropine Sulfate Injection, USP, may be given parenterally as a pre-anesthetic medication in surgical patients to reduce salivation and bronchial secretions. It may also be used to suppress vagal activity associated with the use of halogenated hydrocarbons during inhalation anesthesia and reflex excitation arising from mechanical stimulation during surgery.
Company Information	
Manufacture	International Medication Systems, Limited (IMS) 1886 Santa Anita Avenue, South El Monte, California 91733 Tel (800) 423-4136 Fax (626) 459-5255
Emergency Number	(800) 423-4136 (US Domestic), (909) 980-9484 (International)
SECTION II. HAZARD(S) IDENTIFICATION	
Emergency Overview	Liquid Clear Heat prostration can occur with anticholinergic drug use (fever and heat stroke due to decreased sweating) in the presence of a high environmental temperature. Diarrhea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. Treatment of diarrhea with these drugs is inappropriate and possibly harmful.
Statement of Hazard	Not Applicable
Potential Health Effect	**Gastrointestinal:** Xerostomia; altered taste precepition; nausea; vomiting; dysphagia; heartburn, constipation; bloated feeling; paralytic ileus; gastroesophageal reflux. **Genitourinary:** Urinary hesitancy and retention; impotence. **Ocular:** Blurred vision; mydriasis; photophobia; cycloplegia; increased intraocular pressure. **Cardiovascular:** Palpitations; bradycardia (following low doses of atropine); tachycardia (after higher doses). **Central Nervous System:** Headache; flushing; nervousness; drowsiness; weakness; dizziness; insomnia; fever. Elderly patients may exhibit mental confusion or excitement to

Potential Health Effect (cont.)	even small doses. Large doses may produce CNS stimulation (restlessness, tremor). **Dermatologic – Hypersensitivity:** anaphylaxis, urticaria and other dermal manifestations. **Other:** Suppression of lactation; nasal congestion; decreased sweating. Complete anhidrosis cannot occur because large doses would be required, producing severe side effects from parasympathetic paralysis.	
Hazard Class	Not Applicable	
Hazard Category	GHS Classification	Not applicable
	Classification according to EC Directive 1272/2008	Not available
	Classification according to EC Directives 64/548/EEC (substances) or 1999/45/EC (mixtures)	Not available

SECTION III. COMPOSITION/INFORMATION ON INGREDIENTS		
Active Ingredient	Atropine Sulfate Monohydrate	
	Approximate % by weight: 0.01	RTECS No. CK2455000
	EC Number: Not available	CAS #: 73791-47-6
Inactive Ingredients	Sodium Chloride Citric Acid Sodium Citrate Water for Injection	
Chemical Formula	$C_{17}H_{23}NO_3$	

SECTION IV. FIRST-AID MEASURES	
Eye Contact	Flush eyes immediately with copious amounts of water. Seek medical attention if deemed necessary.
Skin Contact	Avoid direct skin contact. Wash affected skin surfaces immediately with mild soap and copious amounts of water.
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.
Effect and Treatment of Overdosage	Administer supportive and symptomatic therapy as indicated. Physostigmine 1 to 3 mg I.V. has been utilized to reverse anticholinergic effects. However, profound bradycardia, asystole and seizures may occur. The role of physostigmine is not clear; its use should be avoided if other therapeutic agents are successful in reversing cardiac dysrhythmias. Neostigmine methylsulfate 0.5 and 2 mg I.V., repeated as needed, may be given. Diazepam or short-acting barbiturates may control excitement. Hemodialysis is ineffective for atropine poisoning. Hyperpyrexia may be treated with physical cooling measures. If photophobia occurs, the patient may be kept in a dark room.

SECTION V. FIRE-FIGHTING MEASURES	
Extinguishing Media	Water, carbon dioxide, dry chemical or foam.
Special Fire-Fighting Precautions	No special precautions determined for this product.

Flammability		
Fire/Explosion Hazards		None anticipated for this product.
Hazardous Combustion Products		Unknown
Flash Point		Unknown
Auto-Ignition Temperature		Not applicable
Flammable Limits	LEL	Not applicable
	UEL	Not applicable

SECTION VI. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Steps to be Taken if Released or Spilled	Absorb onto paper. Wash spill site with copious amounts of water.

SECTION VII. HANDLING AND STORAGE

Handling	No special handling required under conditions of normal product use.
Storage	Store at controlled room temperature 15° to 30°C (59° to 86°F).

SECTION VIII. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limits	**Component**	**µg/m³**	**Note**
	Atropine Sulfate Monohydrate	4	8hr TWA

Personal Protective Equipment (PPE)	
Eye Protection	Adequate eye protection recommended including safety glasses.
Skin Protection	Adequate skin protection recommended including gloves. Lab coats or additional precaution may be required based on procedure or level of exposure. Consult your site safety staff for guidance.
Respiratory Protection	Respiratory protection is not needed during normal product use.
Engineering Controls	Local ventilation adequate.

SECTION IX. PHYSICAL AND CHEMICAL PROPERTIES

Appearance and Odor	Not applicable
Physical State	Liquid
pH	4.2 (3.0 to 6.5)
Molecular Weight	Unknown
Melting Point(°C)	Not applicable
Freezing Point(°C)	Not applicable
Boiling Point(°C)	Not applicable
Evaporation Rate	Water solvent will slowly evaporate
Vapor Pressure	Not applicable

Vapor Density	Not applicable
Relative Density	Unknown
Solubility(ies)	Miscible in water and alcohol
Partition coefficient	Unknown
Decomposition Temperature	Not applicable
Viscosity	Unknown
Flammability	See **Section V: Fire Fighting Measures** for flammability/explosivity information.

SECTION X. STABILITY AND REACTIVITY

Stability/Reactivity	Atropine sulfate effloresces on exposure to dry air and is slowly affected by light. Atropine should be stored in tight, light-resistant containers at <25°C. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not use if solution is discolored or if it contains a precipitate.
Hazardous Reactions	Not determined.
Incompatibilities/ Conditions to Avoid	Light exposure and temperatures higher than 25°C or freezing temperature.
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.

SECTION XI. TOXICOLOGICAL INFORMATION

The data presented below is for this product or for a structurally similar product.

Acute Toxicity	Test Type	Route of Administration	Value	Units	Species
	LD_{50}	Oral	622	mg/kg	rat

Repeat Dose Toxicity Data

Subchronic/Chronic Toxicity	Not available
Reproductive/ Developmental Toxicity	Reproduction studies performed in mice at doses of 50 mg per kg of body weight have revealed no evidence of impaired fertility or harm to the fetus due to atropine. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.
Mutagenicity/Genot oxicity	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.

SECTION XII. ECOLOGICAL INFORMATION

Ecotoxicity Data	Not determined for this product
Environmental Data	Not determined for this product

SECTION XIII. DISPOSAL CONSIDERATIONS	
Method of Disposal	Approved chemical waste incineration or approved aqueous discharge to municipal or on-site wastewater treatment systems.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.
SECTION XIV. TRANSPORT INFORMATION	
This material is not subject to the transportation regulation of USDOT, EUADR, IATA or IMDG/IMO	
SECTION XV. REGULATORY INFORMATION	
US State Regulations	Check state requirements for ingredient listing
RCRA Status	Not listed
U.S. OSHA Classification	Target Organ Toxin Possible Irritant
TSCA Listing	Not listed
GHS Classification	Not applicable
EU Classification	Not available
Symbol	Not applicable
Response	See First Aid measures **(Section IV)**
SECTION XVI. OTHER INFORMATION	
Pharmaceutical Use	This product is Rx Only. Please follow instructions in the package insert.
Abbreviations	
ADR	Agreement on Dangerous Goods by Road
CAS	Chemical Abstracts Service Number
DOT	US Department of Transportation Regulations
IATA	International Air Transport Association
IMDG/IMO	International Maritime Dangerous Goods Code/International Maritime Organization
LD50	Dosage producing 50% mortality
LEL	Lower Exposure Limit
N/A	Not applicable
OSHA PEL	US Occupational Safety and Health Administration -- Permissible Exposure Limit
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
TSCA	Toxic Substance Control Act
TWA	8-hour time weighted average
UEL	Upper Exposure Limit
Revision Date	07/11/14
Supersedes Date	09/14/12

Rx Only. Refer to package insert for additional information.

The information contained herein is believed to be complete and accurate. However, it is the user's responsibility to determine the suitability of the information for their particular purpose. The company assumes no additional liability or responsibility resulting from the usage of, or reliance on this information.