



INTERNATIONAL MEDICATION SYSTEMS, LIMITED  
 1886 SANTA ANITA AVENUE, SOUTH EL MONTE, CALIFORNIA 91733  
 AREA CODE (800) 423-4136, (909) 980-9484 (INTERNATIONAL)  
 FAX (626) 459-5255

**SAFETY DATA SHEET**

| <b>SECTION I. IDENTIFICATION</b>            |  |
|---|--|
| Identity/Material Name                      | Atropine Sulfate Injection, 0.1 mg/ml, 10 mL   |
| Synonyms                                    | Atropinsulfat, Atropine sulphate   |
| Stock Number                                | 3340   |
| NDC Number                                  | 76329-3340-1   |
| Unit Size                                   | 1 mg / 10 mL (in single use prefilled syringes)  |
| Intended Use                                | <b>Rx Only.</b> 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.  |
| <b>Company Information</b>                  |  |
| Manufacture                                 | International Medication Systems, Limited (IMS)<br>1886 Santa Anita Avenue, South El Monte, California 91733<br>Tel (800) 423-4136<br>Fax (626) 459-5255   |
| Emergency Number                            | (800) 423-4136 (US Domestic), (909) 980-9484 (International)   |
| <b>SECTION II. HAZARD(S) IDENTIFICATION</b> |  |
| Emergency Overview                          | Liquid<br>Clear<br>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.  |
| Hazard Statement(s)                         | Not classified in accordance with international standards for workplace safety.<br>Classification of the Substance or Mixture<br>GHS - Classification Not classified as hazardous  |
| Potential Health Effect                     | <b>Gastrointestinal:</b> Xerostomia; altered taste preception; nausea; vomiting; dysphagia; heartburn, constipation; bloated feeling; paralytic ileus; gastroesophageal reflux.<br><b>Genitourinary:</b> Urinary hesitancy and retention; impotence.<br><b>Ocular:</b> Blurred vision; mydriasis; photophobia; cycloplegia; increased intraocular pressure.<br><b>Cardiovascular:</b> Palpitations; bradycardia (following low doses of atropine); tachycardia (after higher doses). |

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Approved By/Date:

*[Signature]* 1-19-21

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|   |  |              |   |                           |              |
|---|--|--------------|---|---------------------------|--------------|
|   | <p><b>Central Nervous System:</b> Headache; flushing; nervousness; drowsiness; weakness; dizziness; insomnia; fever. Elderly patients may exhibit mental confusion or excitement to even small doses. Large doses may produce CNS stimulation (restlessness, tremor).</p> <p><b>Dermatologic – Hypersensitivity:</b> anaphylaxis, urticaria and other dermal manifestations.</p> <p><b>Other:</b> Suppression of lactation; nasal congestion; decreased sweating. Complete anhidrosis cannot occur because large doses would be required, producing severe side effects from parasympathetic paralysis.</p>  |              |   |                           |              |
| 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             |              |
| Precautionary Statement   | <p>This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.</p> <p>Text of CLP/GHS Classification abbreviations mentioned in Section III.<br/>                     Acute toxicity, oral – Cat.2; H300 - Fatal if swallowed<br/>                     Acute toxicity, inhalation – Cat.2; H330 - Fatal if inhaled<br/>                     Skin corrosion/irritation – Cat.1A; H314 - Causes severe skin burns and eye damage</p> <p>An Occupational Exposure Value has been established for one or more of the ingredients (see Section VIII). For a more detailed discussion of potential health hazards and toxicity see Section XI.</p> |              |   |                           |              |
| Label / Signal Word   | Signal Word: Not Classified  |              |   |                           |              |
| <b>SECTION III. COMPOSITION/INFORMATION ON INGREDIENTS</b>  |  |              |   |                           |              |
| Active Ingredient   | Atropine Sulfate   |              |   |                           |              |
|   | Approximate % by weight: 0.01 %  |              | GHS Classification:<br>Acute Tox. 2 (H300)<br>Acute Tox. 2 (H330) |                           |              |
|   | EC Number: 200-235-0   |              | CAS #: 5908-99-6  |                           |              |
| Inactive Ingredients  | <b>Ingredients</b>   | <b>CAS #</b> | <b>EINECS #</b>   | <b>GHS Classification</b> | <b>%</b>     |
|   | Sodium chloride  | 7647-14-5    | 231-598-3   | Not listed                | *            |
|   | Sodium hydroxide   | 1310-73-2    | 215-185-5   | Skin Corr. 1A (H314)      | To adjust pH |
|   | Sulfuric acid  | 7664-93-9    | 231-639-5   | Skin Corr. 1A (H314)      | To adjust pH |
|   | Water for Injection  | 7732-18-5    | 231-791-2   | Not Listed                | *            |
| * Proprietary. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. |  |              |   |                           |              |
| Chemical Formula  | C <sub>34</sub> H <sub>46</sub> N <sub>2</sub> O <sub>6</sub> · H <sub>2</sub> SO <sub>4</sub> · H <sub>2</sub> O  |              |   |                           |              |

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| <b>SECTION IV. FIRST-AID MEASURES</b>          |  |                |
|--|--|----------------|
| 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. |                |
| <b>SECTION V. FIRE-FIGHTING MEASURES</b>       |  |                |
| Extinguishing Media                            | Water, carbon dioxide, dry chemical or foam.   |                |
| Special Fire-Fighting Precautions              | No special precautions determined for this product.  |                |
| <b>Flammability</b>                            |  |                |
| 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 |
| <b>SECTION VI. ACCIDENTAL RELEASE MEASURES</b> |  |                |
| 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.  |                |
| <b>SECTION VII. HANDLING AND STORAGE</b>       |  |                |
| Handling                                       | Pharmaceutical drug product. Please following labeling instructions. No other special handling required under conditions of normal product use.  |                |
| Storage  | Store at controlled room temperature 15° to 30°C (59° to 86°F).  |                |

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| SECTION VIII. EXPOSURE CONTROLS/PERSONAL PROTECTION |   |                     |                          |
|---|---|---------------------|--------------------------|
| Exposure Limits                                     | Component   | Control Level       | Note                     |
|   | Atropine Sulfate Monohydrate  | 4 µg/m <sup>3</sup> | 8hr TWAs                 |
|   | Sodium hydroxide  | 2 mg/m <sup>3</sup> | OSHA - Final PELs – TWAs |
|   | Sulfuric acid   | 1 mg/m <sup>3</sup> | OSHA - Final PELs – TWAs |
| 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  | 3.0 to 6.5  |                     |                          |
| 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 <b>Section V: Fire Fighting Measures</b> for flammability/explosivity information.  |                     |                          |
| SECTION X. STABILITY AND REACTIVITY                 |   |                     |                          |
| Stability/Reactivity                                | Stable under normal conditions of use per labeling. 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.   |                     |                          |

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|---|--|-------------------------|-------|-------|---------|
| Incompatibilities/<br>Conditions to Avoid   | Light exposure and temperatures higher than 25°C or freezing temperature.  |                         |       |       |         |
| Hazardous Decomposition<br>Products   | Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ), and sulfur oxides (SO <sub>x</sub> ).   |                         |       |       |         |
| Hazardous Polymerization  | Not anticipated to occur with this product.  |                         |       |       |         |
| <b>SECTION XI. TOXICOLOGICAL INFORMATION</b>  |  |                         |       |       |         |
| 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 <sub>50</sub>   | Oral                    | 622   | mg/kg | rat     |
| <b>Repeat Dose Toxicity Data</b>  |  |                         |       |       |         |
| Subchronic/Chronic<br>Toxicity  | Not available  |                         |       |       |         |
| Reproductive/<br>Developmental<br>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/<br>Genotoxicity   | 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.  |                         |       |       |         |
| <b>SECTION XII. ECOLOGICAL INFORMATION</b>  |  |                         |       |       |         |
| Ecotoxicity Data  | Not determined for this product  |                         |       |       |         |
| Environmental Data  | Not determined for this product  |                         |       |       |         |
| <b>SECTION XIII. DISPOSAL CONSIDERATIONS</b>  |  |                         |       |       |         |
| Method of Disposal  | Approved chemical waste incineration or approved aqueous discharge to municipal or on-site wastewater treatment systems.   |                         |       |       |         |
| Container Handling and<br>Disposal  | Dispose of container and unused contents in accordance with federal, state and local regulations.  |                         |       |       |         |
| <b>SECTION XIV. TRANSPORT INFORMATION</b>   |  |                         |       |       |         |
| This material is not subject to the transportation regulation of USDOT, EUADR, IATA or IMDG/IMO |  |                         |       |       |         |
| <b>SECTION XV. REGULATORY INFORMATION</b>   |  |                         |       |       |         |
| US State Regulations  | Check state requirements for ingredient listing  |                         |       |       |         |
| RCRA Status   | Not listed   |                         |       |       |         |
| U.S. OSHA Classification  | Target Organ Toxin<br>Possible Irritant  |                         |       |       |         |
| TSCA Listing  | Not listed   |                         |       |       |         |
| GHS Classification  | Not applicable   |                         |       |       |         |
| EU Classification   | Not available  |                         |       |       |         |

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|---------------------------------------|--|-----|--------------------------------------|-----|-----------------------------------|-----|---|------|---|----------|---|------|--------------------------------|-----|----------------------|-----|----------------|----------|---|------|--|-------|--|------|-----------------------------|-----|------------------------------|-----|----------------------|-------|--|
| Symbol                                | Not applicable   |     |                                      |     |                                   |     |   |      |   |          |   |      |                                |     |                      |     |                |          |   |      |  |       |  |      |                             |     |                              |     |                      |       |  |
| Response                              | See First Aid measures (Section IV)  |     |                                      |     |                                   |     |   |      |   |          |   |      |                                |     |                      |     |                |          |   |      |  |       |  |      |                             |     |                              |     |                      |       |  |
| <b>SECTION XVI. OTHER INFORMATION</b> |  |     |                                      |     |                                   |     |   |      |   |          |   |      |                                |     |                      |     |                |          |   |      |  |       |  |      |                             |     |                              |     |                      |       |  |
| Pharmaceutical Use                    | This product is <b>Rx Only</b> . Please follow instructions in the package insert.   |     |                                      |     |                                   |     |   |      |   |          |   |      |                                |     |                      |     |                |          |   |      |  |       |  |      |                             |     |                              |     |                      |       |  |
| Abbreviations                         | <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">ADR</td> <td>Agreement on Dangerous Goods by Road</td> </tr> <tr> <td>CAS</td> <td>Chemical Abstracts Service Number</td> </tr> <tr> <td>DOT</td> <td>US Department of Transportation Regulations</td> </tr> <tr> <td>IATA</td> <td>International Air Transport Association</td> </tr> <tr> <td>IMDG/IMO</td> <td>International Maritime Dangerous Goods Code/International Maritime Organization</td> </tr> <tr> <td>LD50</td> <td>Dosage producing 50% mortality</td> </tr> <tr> <td>LEL</td> <td>Lower Exposure Limit</td> </tr> <tr> <td>N/A</td> <td>Not applicable</td> </tr> <tr> <td>OSHA PEL</td> <td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td> </tr> <tr> <td>RCRA</td> <td>US EPA, Resource Conservation and Recovery Act</td> </tr> <tr> <td>RTECS</td> <td>Registry of Toxic Effects of Chemical Substances</td> </tr> <tr> <td>TSCA</td> <td>Toxic Substance Control Act</td> </tr> <tr> <td>TWA</td> <td>8-hour time weighted average</td> </tr> <tr> <td>UEL</td> <td>Upper Exposure Limit</td> </tr> <tr> <td>WHMIS</td> <td>Workplace Hazardous Materials Information System</td> </tr> </table> | 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 | WHMIS | Workplace Hazardous Materials Information System |
| 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   |     |                                      |     |                                   |     |   |      |   |          |   |      |                                |     |                      |     |                |          |   |      |  |       |  |      |                             |     |                              |     |                      |       |  |
| WHMIS                                 | Workplace Hazardous Materials Information System   |     |                                      |     |                                   |     |   |      |   |          |   |      |                                |     |                      |     |                |          |   |      |  |       |  |      |                             |     |                              |     |                      |       |  |
| Effective Date                        | 01/14/21   |     |                                      |     |                                   |     |   |      |   |          |   |      |                                |     |                      |     |                |          |   |      |  |       |  |      |                             |     |                              |     |                      |       |  |

**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.

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