



Material Safety Data Sheet

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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: Atropine Sulfate Injection, USP
Product code: NDC 0641-6006-01 NDC 0641-6006-10
Chemical Family: Anticholinergic Agent.
Product Type: Regulated Prescription Drug
Container Information: 20 ml vials
Product Use: Preanesthetic

Supplier:
WEST-WARD PHARMACEUTICALS
EATONTOWN, NJ 07724

Emergency telephone number: CHEMTREC: USA & Canada (800) 424-9300 OUTSIDE USA +1 703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Atropine sulfate 55-48-1	0.04-0.1	None	Xn; R22
Sodium Chloride 7647-14-5	<1	None	Xi; R38
Benzyl Alcohol 100-51-6	<1	UN1986 (flammable, toxic); UN1987 (alcohol); UN3065 (alcoholic beverages)	Xn; R20/22
Water 7732-18-5	>98	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: Product contains no specific hazards other than therapeutic effects.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions.

Ingestion: No known effect according to our database.

Skin contact: May cause skin irritation.

Eye contact: May cause eye irritation.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

Skin contact: In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.

Ingestion: Do not induce vomiting unless directed by a physician. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

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4. FIRST AID MEASURES

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Notes to physician: See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media: Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters: Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods: No information available.
Flash point: Not determined
Autoignition temperature: Not available
Flammable limits in air-lower (%): Not available
Flammable limits in air-upper (%): Not available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions: No information available.

Methods for cleaning up: If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Wash thoroughly after handling.

Storage:

Technical measures/storage conditions: Keep containers tightly closed in a dry, cool and well-ventilated place. Store between 15-30°C (59 to 86°F).

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Atropine sulfate 55-48-1	None	None	None	None	None	None
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Benzyl Alcohol 100-51-6	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering measures:	Good general ventilation should be sufficient to control airborne levels.
<u>Personal protective equipment:</u>	
Respiratory protection:	Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.
Hand protection:	Use chemical resistant, impervious gloves.
Skin and body protection:	Work uniform or laboratory coat.
Eye protection:	Safety glasses with side-shields. Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Liquid
Appearance:	Aqueous solution
Color:	Colorless
Odor:	Odorless
pH:	3 - 4.5
Molecular weight:	Not available.
Boiling point/range:	Not available.
Melting point/range:	May start to solidify at 0°C (32°F) based on data for: Water.
Density:	Not available.
Vapor pressure:	Not available.
Evaporation rate:	Not available.
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Viscosity:	Not available.
% Volatile by Volume:	Not available.

10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Polymerization:	Not applicable
Hazardous decomposition products:	Not available.
Materials to avoid:	Oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Atropine sulfate 55-48-1	Oral LD50 Rat = 600 mg/kg Oral LD50 Mouse = 468 mg/kg Intravenous LD50 Rat = 41 mg/kg Intravenous LD50 Mouse = 31 mg/kg Intravenous LD50 Dog = 60 mg/kg Intravenous LD50 Rabbit = 70 mg/kg
Sodium Chloride 7647-14-5	Inhalation LC50 Rat >42 gm/m ³ /1H Oral LD50 Rat = 3 gm/kg Oral LD50 Mouse = 4 gm/kg Dermal LD50 Rabbit >10 gm/kg
Benzyl Alcohol 100-51-6	Oral LD50 Rat = 1230 mg/kg Oral LD50 Mouse = 1360 mg/kg Dermal LD50 Rabbit = 2 gm/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

Acute toxicity: Signs and symptoms of overdosage may include delirium, increased heart rate, and fever.

Chronic toxicity: Contains material which may cause damage to the following organs: skin, eye, lens or cornea. Target Organs: Nervous System.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on the product itself.

Mutagenic effects: No data is available on the product itself.

Reproductive toxicity: No data is available on the product itself.

FDA Pregnancy Category C

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Microtox Ecotoxicity Data
Atropine sulfate 55-48-1	None.	None.	None.	None.
Sodium Chloride 7647-14-5	None.	None.	None.	None.
Benzyl Alcohol 100-51-6	= 23 mg/L EC50 water flea	LC50 (96 hr) fathead minnow: 460 mg/L: Static, 18-22 °C.; LC50 (96 hr) bluegill: 10 mg/L: Static.	None.	= 63.7 mg/L EC50 Photobacterium phosphoreum = 71.4 mg/L EC50 Photobacterium phosphoreum
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

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13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name: None
UN Number: None
DOT Packing Group: None
DOT Hazard class: None

TDG (Canada):

TDG Proper shipping name: None
TDG UN/NA Number: None
TDG Packing Group: None
TDG Hazard class: None

ADR/RID:

ADR Official Transport Name: None
ADR Proper shipping name: None
ADR UN/NA number: None
ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None
IATA UN NUMBER: None
IATA Primary Hazard: None
IATA Packing group: None
ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None
IMDG Hazard Class and Division: None
IMDG Packing Group: None
IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS) This product complies with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Atropine sulfate	0.04-0.1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	<1	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	<1	Not Listed	Not Listed	Not Listed	Not Listed
Water	>98	Not Listed	Not Listed	Not Listed	Not Listed

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15. REGULATORY INFORMATION

STATE REGULATIONS:

Component	California Prop 65:	Minnesota Right-To-Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Atropine sulfate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	Not Listed	Present	Not Listed	Not Listed	Present	[present]	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product complies with DSL

EU EINECS List - This product complies with EINECS

Risk Phrases:
NONE

Safety Phrases:
NONE

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):
Updated company name from Baxter to West-Ward. Updated NDC codes

Additional information:
Not Available.

Prepared by: West-Ward Pharmaceuticals

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of safety data sheet

Product name: Atropine Sulfate Injection