

ATROPINE SULFATE INJECTION, USP

Safety Data Sheet



According to 29 CFR 1910.1200 (g) [Federal Register Vol. 77, No. 58 Dated March 26, 2012]

Date of Issue: 11/10/2022

Revision: 000

1. IDENTIFICATION

(a) **Product Identifier:**

Product Name: Atropine Sulfate Injection, USP, 1 mg/10 mL (0.1 mg/mL)
Trade Name: Atropine Sulfate Injection, USP
Chemical Family: Mixture

(b) **Intended Use of the Product:**

Indicated for temporary blockage of severe or life threatening muscarinic effects., e.g., as an antispasmodic, an anticholinergic agent, an antidote for organophosphorus or muscarinic mushroom poisoning, and to treat bradycardic cardiac arrest.

(c) **Name, Address, Telephone of the Manufacturer:**

Medefil, Inc.
405 Windy Point Drive
Glendale Heights, IL. 60139
(630) 682 – 4600
www.medefilinc.com

(d) **Emergency Telephone Number:** 1-630-682-4600

2. HAZARDS IDENTIFICATION

(a) **Classification of the Substance of Mixture**

GHS-US Classification: Not classified as hazardous

(b) **Label Elements**

Signal Word (GHS-US): Not Classified
Hazard Statements (GHS-US): Not classified in accordance with international standards for workplace safety.

(c) **Other Hazards:** An Occupational Exposure Value has been established for one or more ingredients (see Section 8).

(d) **Unknown Acute Toxicity (GHS-US):** No data available

(e) **Additional Information:** For a more detailed discussion of potential health hazards and toxicity see Section 11.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture

Name	CAS Number	%	GHS-US Classification
Atropine sulfate monohydrate	5908-99-6	0.01	Acute Toxicity (H300) Acute Toxicity (H330)
Sodium chloride	7647-14-5	0.9	Not classified as hazardous
Water for Injection	7732-18-5	91	Not classified as hazardous
Sulfuric Acid*	7664-93-9	-	Skin Corr. 1A, H314
Sodium Hydroxide*	1310-73-2	-	Skin Corr. 1A, H314

* to adjust pH

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For full text of H-phrases, see Section 16

4. FIRST AID MEASURES

4.1 Description of First-aid Measures

- General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.
- Skin Contact:** Remove contaminated clothing. Wash affected area with plenty of soap and water. Obtain medical attention if irritation develops or persists.
- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Obtain medical attention if irritation occurs or persists.
- Ingestion:** Rinse mouth with water. Do NOT induce vomiting unless directed by medical personnel. Seek medical attention.
- Inhalation:** Move to fresh air and ventilate suspected area. If discomfort occurs, seek medical attention/advice.

4.2 Most Important Symptoms and Effects Both Acute and Delayed

Not expected to present a significant hazard under anticipated conditions of normal use. See Section 2 – Hazards Identification and/or Section 11 – Toxicological Information.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, seek medical advice and attention. If medical advice is needed, have product container or label at hand.

5. FIRE-FIGHTING MEASURES

5.1. **Extinguishing Media:** As for primary cause of fire.

5.2. Special Hazards Arising from the Substance or Mixture:

Specific hazards arising from the chemical: Not applicable.
Hazardous combustion products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon and products of nitrogen.

5.3. **Advice for Firefighters:** During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

Personal Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Emergency Responders: Use personal protection recommended in Section 8.

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6.2. Environmental Precautions

Place waste in appropriately labeled, sealed container for disposal. Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

Methods for containment: Prevent further leakage or spillage if safe to do so.
Methods for clean up: Contain the source of spill, if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

6.4 Reference to Other Sections

See section 8 for more information. See Section 13 for more information.

7. HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapors, mist, and spray. Avoid contact with skin, eyes and clothing. Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store as directed by product packaging. Do not refrigerate.
Incompatible Products: Strong bases. Strong oxidizers

7.3 Specific End Use(s):

Atropine Sulfate Injection, USP is indicated for temporary blockage of severe or life threatening muscarinic effects., e.g., as an antispasmodic, an anticholinergic agent, an antidote for organophosphorus or muscarinic mushroom poisoning, and to treat bradycardic cardiac arrest.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 **Control Parameters:** Refer to available public information for specific member state Occupational Exposure Limits.
For substances listed in Section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL)

Atropine Sulfate, Monohydrate:	OEL, TWA-8 hour:	4 µg/m ³ .
Sulfuric Acid:	ACGIH Ceiling Threshold Limit:	0.2 mg/m ³ .
Sodium Hydroxide:	ACGIH Ceiling Threshold Limit:	2 mg/m ³ .

8.2 Exposure Controls:

Appropriate Engineering Controls: Engineering controls should be used as the primary means to control exposure. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section. Ensure all national/local regulations are observed.

Environmental Exposure Controls: No Information available

Personal Protective Equipment: Contact your safety and health professional or safety

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Materials for Protective Clothing:

Hand Protection:

Eye Protection:

Skin and Body Protection:

Respiratory Protection:

Other Information:

equipment supplier for assistance in selecting correct protective clothing/equipment on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Chemically resistant materials and fabrics.

Wear chemically resistant protective gloves.

Chemical safety goggles.

Wear suitable protective clothing.

If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State:	Liquid
Appearance:	Clear, colorless solution
Odor:	Odorless
Odor Threshold:	No data available
pH:	3.0 - 6.5
Evaporation Rate:	No data available
Melting Point:	No data available
Freezing Point:	No data available
Boiling Point:	No data available
Flash Point:	No data available
Auto-ignition Temperature:	No data available
Decomposition Temperature:	No data available
Flammability (solid, gas):	No data available
Vapor Pressure:	No data available
Relative Vapor Density at 20°C:	No data available
Specific Gravity:	≈ 1.1
Solubility:	Water: Freely soluble in water
Partition Coefficient:	N-Octanol/Water: No data available
Viscosity:	No data available
Calcium Chloride, USP:	No data available
Hydrochloric Acid:	No data available
Sodium Hydroxide:	No data available
Water for Injection, USP:	No data available

9.2. **Other Information** No additional information available.

10. STABILITY AND REACTIVITY

- 10.1. **Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. **Chemical Stability:** Stable under recommended handling and storage conditions (see Section 7).
- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.

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- 10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers. Zinc. Bromine trifluoride.
- 10.6. **Hazardous Decomposition Products:** Thermal decomposition products may include Hydrogen chloride gas, chlorine.

11 TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects:

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause central nervous system effects.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety and dilated pupils. Cases of severe overdose may lead to respiratory depression.

Acute Toxicity: (Species, Route, End Point, Dose)

Water (7732-18-5)			
Rat	Oral	LD50	> 90000 mg/Kg
Mouse	Oral	LD50	1940 mg/Kg

Atropine Sulfate (55-48-1)			
Rat	Oral	LD50	500 – 600 mg/Kg
ATE (Dust/Mist)			0.05 mg/l/4h

Sodium Chloride (7647-14-5)			
Rat	Oral	LD50	3 g/Kg
Rat	Inhalation	LC50	> 42 g/m ³ (Exposure Time: 1 h)
Mouse	Oral	LD50	4 g/Kg
Rabbit	Dermal	LD50	> 10 g/Kg

Sulfuric Acid (7664-93-9)			
Rat	Oral	LD50	2140 mg/Kg
Rat	Inhalation	LC50	510 mg/m ³ (Exposure Time: 2 h)

Hydrochloric Acid (7647-01-0)			
Rat	Oral	LD50	238 – 277 mg/Kg

Irritation / Sensitization: (Study Type, Species, Severity)

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Skin Corrosion / Irritation:	Not Classified	pH: 3 – 4.5
Serious Eye Damage / Irritation:	Not Classified	pH: 3 – 4.5
Respiratory or Skin Sensitization:	Not Classified	
Germ Cell Mutagenicity:	Not Classified	
Carcinogenicity:		

Atropine Sulfate, monohydrate (55-48-1)	
Additional Information	The International Agency for Research on Cancer (IARC) and United States National Toxicology Program (NTP) have classified *occupational exposure to

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	strong inorganic acid mists containing sulfuric acid' as a known human carcinogen. The classification only applies to sulfuric acid when generate as a mist.
Sulfuric Acid (7664-93-9)	
IARC Group	1

Reproductive Toxicity: Not Classified
 Specific Target Organ Toxicity (Single Exposure): Not Classified
 Specific Target Organ Toxicity (Repeated Exposure): Not Classified
 Aspiration Hazard: Not Classified

12 ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

- 12.1 **Toxicity:** No data available.
- 12.2 **Persistence and Degradability:** No data available.
- 12.3 **Bio-accumulative Potential:** No data available .
- 12.4 **Mobility in Soil:** No data available.

13 DISPOSAL CONSIDERATIONS

- 13.1 **Waste Treatment Methods:** Dispose of contents/container in accordance with local, regional, national, and international regulations. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practices. This may include destructive techniques for waste and waste water.
- 13.2 **Ecology – Waste Materials:** Avoid release to the environment.

14 TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below

- 14.1 **In Accordance with DOT:** Not regulated for transport.
- 14.2 **In Accordance with IMDG:** Not regulated for transport.
- 14.3 **In Accordance with IATA:** Not regulated for transport.

15 REGULATORY INFORMATION

Atropine Sulfate Monohydrate, USP
 CERCLA/SARA313 Emission reporting Not listed

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California Proposition 65	Not listed
Inventory – United States TSCA – Sec. 8(b)	Present

Sodium Chloride, USP

CERCLA/SARA313 Emission reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sec. 8(b)	Present

Water for Injection, USP

CERCLA/SARA313 Emission reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sec. 8(b)	Present

Sulfuric Acid

CERCLA/SARA313 Emission reporting	1.0%
CERCLA/SARA Hazardous substances	1000 lbs
And their reportable quantities:	454 Kg
CERCLA/SARA – Section 302 Extremely Hazardous TPQs	1000 lbs
CERCLA/SARA – Section 302 Extremely Hazardous EPCRA RQs	1000 lbs
California Proposition 65	Not listed
Inventory – United States TSCA – Sec. 8(b)	Present

Sodium Hydroxide

CERCLA/SARA313 Emission reporting	Not listed
CERCLA/SARA Hazardous substances	1000 lbs
And their reportable quantities:	454 Kg
California Proposition 65	Not listed
Inventory – United States TSCA – Sec. 8(b)	Present

16 OTHER INFORMATION

Date of Preparation of Latest Information:	November 10, 2022
Other Information:	This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 2 (Inhalation: Dust, Mist)	Acute toxicity (inhalation: dust, mist) Category 2
Acute Tox. 4 (Oral)	Acute Toxicity (Oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment – Acute Hazard Category 3
Carc. 1A	Carcinogenicity Category 1A
Eye Dam. 1	Serious eye damage / eye irritation Category 1
Skin Corr. 1A	Skin corrosion / irritation Category 1A
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H330	Fatal if inhaled
H350	May cause cancer
H405	Harmful to aquatic life

Refer to Prescribing Information for further information at www.medefilinc.com

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