

# SAFETY DATA SHEET

## Atropine Sulfate Injection, USP (0.4 mg/mL and 1 mg/mL (1 mL))

### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

**Product Identifier**

**Material Name:** Atropine Sulfate Injection, USP [0.4 mg/mL and 1 mg/mL (1 mL)]

**Trade Name:** Atropine Sulfate Injection, USP

**Chemical Family:** Mixture

**Intended Use:** temporary blockade of severe or life threatening muscarinic effects, e.g., as an antisialagogue, an antivagal agent, an antidote for organophosphorus or muscarinic mushroom poisoning, and to treat bradycardiac arrest

**Details of the Supplier of the**

**Safety Data Sheet** Somerset Therapeutics, LLC. Somerset, NJ 08873

**Customer Care** 1-800-417-9175

### 2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**

**GHS - Classification** Not classified as hazardous

**Label Elements**

**Signal Word:** Not Classified

**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

**Other Hazards**

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

**Note:** 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.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

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

**Hazardous**

Ingredient	CAS Number
Atropine Sulfate, USP	5908-99-6
Sodium Chloride, USP	7647-14-5
Sulfuric acid, NF	7664-93-9
Sodium Hydroxide, NF	1310-73-2
Water for Injection, USP	In-House

**Additional Information:**

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.

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For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. If irritation occurs or persists, get medical attention.
- Skin Contact:** Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions:** None known
- Aggravated by Exposure:** Indication of the Immediate Medical Attention and Special Treatment Needed
- Notes to Physician:** **None**

### 5. FIRE FIGHTING MEASURES

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

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire. May include oxides of carbon and products of nitrogen

**Fire / Explosion Hazards:** Not applicable

#### Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Avoid breathing mist or aerosols. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Incompatible Materials:** None

**Specific end use(s):** Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### SODIUM CHLORIDE

Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	5 mg/m <sup>3</sup>

#### SODIUM HYDROXIDE

ACGIH Ceiling Threshold Limit:	2 mg/m <sup>3</sup>
Australia PEAK	2 mg/m <sup>3</sup>
Austria OEL - MAKs	2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	2.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
Estonia OEL - TWA	1 mg/m <sup>3</sup>
France OEL - TWA	2 mg/m <sup>3</sup>
Greece OEL - TWA	2 mg/m <sup>3</sup>
Hungary OEL - TWA	2 mg/m <sup>3</sup>
Japan - OELs - Ceilings	2 mg/m <sup>3</sup>

#### Atropine Sulfate, USP

Somerset OEL TWA-8 Hr:	4µg/m <sup>3</sup>
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#### Sulfuric acid, NF

ACGIH Threshold Limit Value (TWA)	0.2 mg/m <sup>3</sup>
Australia STEL	3 mg/m <sup>3</sup>
Australia TWA	1 mg/m <sup>3</sup>
Austria OEL - MAKs	0.1 mg/m <sup>3</sup>
Belgium OEL - TWA	0.2 mg/m <sup>3</sup>
Bulgaria OEL - TWA	0.05 mg/m <sup>3</sup>
Cyprus OEL - TWA	0.05 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1 mg/m <sup>3</sup>
	0.05 mg/m <sup>3</sup>
Denmark OEL - TWA	0.05 mg/m <sup>3</sup>

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Estonia OEL - TWA	1 mg/m <sup>3</sup>
Finland OEL - TWA	0.05 mg/m <sup>3</sup>
France OEL - TWA	0.05 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	0.1 mg/m <sup>3</sup>
Germany (DFG) - MAK	0.1 mg/m <sup>3</sup>
Greece OEL - TWA	0.05 mg/m <sup>3</sup>
Hungary OEL - TWA	0.05 mg/m <sup>3</sup>
Ireland OEL - TWAs	0.05 ppm
Italy OEL - TWA	0.05 mg/m <sup>3</sup>
Japan - OELs - Ceilings	1 mg/m <sup>3</sup>
Latvia OEL - TWA	0.05 mg/m <sup>3</sup>
Lithuania OEL - TWA	0.05 mg/m <sup>3</sup>
Luxembourg OEL - TWA	0.05 mg/m <sup>3</sup>
Malta OEL - TWA	0.05 mg/m <sup>3</sup>
Netherlands OEL - TWA	0.05 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	1 mg/m <sup>3</sup>
Poland OEL - TWA	0.05 mg/m <sup>3</sup>
Portugal OEL - TWA	0.05 mg/m <sup>3</sup>
Romania OEL - TWA	0.05 mg/m <sup>3</sup>
Slovakia OEL - TWA	0.1 mg/m <sup>3</sup>
Slovenia OEL - TWA	0.05 mg/m <sup>3</sup>
Spain OEL - TWA	0.05 mg/m <sup>3</sup>
Sweden OEL - TWAs	0.1 mg/m <sup>3</sup>
Switzerland OEL - TWAs	0.1 mg/m <sup>3</sup>
Vietnam OEL - TWAs	1 mg/m <sup>3</sup>

### SODIUM CHLORIDE, USP

Somerset Occupational Exposure Band (OEB):

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. 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.

### Personal Protective Equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Liquid  
**Odor:** No data available.  
**Molecular Formula:** Mixture  
**Color:** Colorless  
**Odor Threshold:** No data available.  
**Molecular Weight:** Mixture

**Solvent Solubility:** No data available  
**Water Solubility:** Soluble  
**pH:** 3.30 (3.20-3.40)  
**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available.  
**Partition Coefficient: (Method, pH, Endpoint, Value)**

#### Water for Injection

No data available

#### Atropine sulfate, monohydrate

No data available

#### SODIUM HYDROXIDE

No data available

#### SODIUM CHLORIDE

No data available

#### Sulfuric acid, NF

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

#### Flammability:

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

**Polymerization:** Will not occur

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### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	None
<b>Conditions to Avoid:</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	None
<b>Hazardous Decomposition Products:</b>	Thermal decomposition products include oxides of carbon, nitrogen, and sulfur.

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients.
<b>Short Term:</b>	May cause central nervous system effects.
<b>Known Clinical Effects:</b>	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)

##### Atropine Sulfate, USP

Rat Oral LD50 500-600 mg/kg

##### SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>

Rat Oral LD 50 3g/kg

Mouse Oral LD 50 4g/kg

Rabbit Dermal LD 50 > 10g/kg

##### Sulfuric acid, NF

Rat Oral LD50 2140 mg/kg

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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

##### SODIUM CHLORIDE

Skin	Rabbit	Mil
Irritation	Rabbit	d
Eye		Mild
Irritation		

##### Sulfuric acid

Eye Irritation	Rabbit	Severe
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## Atropine Sulfate Injection, USP (0.4 mg/mL and 1 mg/mL (1 mL)

### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

#### Atropine Sulfate, USP

Embryo / Fetal Development Oral 50 mg/kg LOEL Developmental toxicity, Maternal  
 toxicity Embryo / Fetal Development Rat Not Teratogenic  
 Embryo / Fetal Development Dog LOEL Not Teratogenic  
 Reproductive & Fertility-Females Rat Subcutaneous 200 mg/kg LOEL Fertility

### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

#### Atropine sulfate, monohydrate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

### Carcinogen Status:

The International Agency for Research on Cancer (IARC) and the United States National Toxicology Program (NTP) have classified 'occupational exposure to strong inorganic acid mists containing sulfuric acid' as a known human carcinogen. This classification applies only to sulfuric acid when generated as a mist. This classification is debated within the scientific community and there is disagreement as to whether or not a cause and effect relationship between cancer and 'occupational exposure to strong inorganic acid mists containing sulfuric acid' exists.

#### Sulfuric acid, NF

IARC: Group 1 (Carcinogenic to Humans)

## 12. ECOLOGICAL INFORMATION

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

**Toxicity:** No data available

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

## 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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 practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### SODIUM CHLORIDE, USP

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Present
	231-598-3

#### Water for Injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	Present
	231-791-2

#### SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable	1000 lb
	454 kg

#### Quantities:

California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	215-185-5

#### Atropine Sulfate, USP

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65 Inventory - United States TSCA - Sect. 8(b)	Not Listed
	Listed



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## Atropine Sulfate Injection, USP (0.4 mg/mL and 1 mg/mL (1 mL)

Australia (AICS):	Present
EU EINECS/ELINCS List	200-235-0

**Sulfuric acid, NF**

CERCLA/SARA 313 Emission reporting	1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	1000 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	1000 lb
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 6
EU EINECS/ELINCS List	231-639-5

### 16. OTHER INFORMATION

**Text of CLP/GHS Classification abbreviations mentioned in Section 3**

Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed  
 Acute toxicity, inhalation-Cat.2; H330 - Fatal if inhaled  
 Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Revision date:** 05.07.2024

**Prepared by:** Somerset Therapeutics Limited

Somerset Therapeutics Limited believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**