



# SAFETY DATA SHEET

Revision date 16-Aug-2022

Version 1.01

Page 1 / 12

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
**Product Code(s)** PZ03250  
**Trade Name:** Atropine Sulfate Injection, USP  
**Chemical Family:** Mixture

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as Anticholinergic agent

### 1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Hospira UK Limited  
Horizon  
Honey Lane  
Hurley  
Maidenhead, SL6 6RJ  
United Kingdom

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

Not classified as hazardous

### 2.2. Label elements

**Signal word** Not Classified

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

### 2.3. Other hazards

**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 require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
Revision date 16-Aug-2022

Page 2 / 12  
Version 1.01

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

#### Substances

Not applicable

### 3.2 Mixtures

#### Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 0.5%≤C<2% Skin Corr. 1A :: C≥5% Skin Corr. 1B :: 2%≤C<5% Skin Irrit. 2 :: 0.5%≤C<2%	No data available	No data available
+ Sulfuric acid (CAS #: 7664-93-9)	**	-	231-639-5	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 5%≤C<15% Skin Corr. 1A :: C≥15% Skin Irrit. 2 :: 5%≤C<15%	No data available	No data available
Atropine sulfate, monohydrate (CAS #: 5908-99-6)	0.005	-	200-235-0	Acute Tox. 2 (H300) Acute Tox. 2 (H330)	Not Listed	No data available	No data available

#### NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

#### Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
Sodium hydroxide	325	1350	No data available	No data available	No data available

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
Revision date 16-Aug-2022

Page 3 / 12  
Version 1.01

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
1310-73-2					
+ Sulfuric acid 7664-93-9	2140	No data available	0.375	No data available	No data available
Atropine sulfate, monohydrate 5908-99-6	500	No data available	No data available	No data available	No data available

## Additional information

\* Proprietary

\*\* to adjust pH

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. Non-hazardous ingredients provided for completeness.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Flush with water while holding eyelids open for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin contact</b>	Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.
<b>Ingestion</b>	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.

### 4.2. Most important symptoms and effects, both acute and delayed

**Most important symptoms and effects** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Note to physicians** None.

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

**Suitable 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

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
Revision date 16-Aug-2022

Page 4 / 12  
Version 1.01

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 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 (see Section 8). Minimize exposure.  
**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

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

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.  
**Methods for cleaning up** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.  
**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## Section 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

#### Advice on 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.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

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

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical drug product.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure Limits

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

#### Atropine sulfate, monohydrate

Pfizer OEL TWA-8 Hr: 4 µg/m<sup>3</sup>

#### SODIUM CHLORIDE

Latvia

5 mg/m<sup>3</sup>

Russia

MAC: 5 mg/m<sup>3</sup>

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
Revision date 16-Aug-2022

Page 5 / 12  
Version 1.01

## Sodium hydroxide

ACGIH OEL (Ceiling)	2 mg/m <sup>3</sup>
ACGIH TLV	Ceiling: 2 mg/m <sup>3</sup>
Austria	2 mg/m <sup>3</sup>
	STEL 4 mg/m <sup>3</sup>
Bulgaria	2.0 mg/m <sup>3</sup>
Czech Republic	1 mg/m <sup>3</sup>
	Ceiling: 2 mg/m <sup>3</sup>
Denmark	Ceiling: 2 mg/m <sup>3</sup>
Estonia	1 mg/m <sup>3</sup>
	STEL: 2 mg/m <sup>3</sup>
Finland	Ceiling: 2 mg/m <sup>3</sup>
France	2 mg/m <sup>3</sup>
Hungary	1 mg/m <sup>3</sup>
	STEL: 2 mg/m <sup>3</sup>
Ireland	STEL: 2 mg/m <sup>3</sup>
Ceiling Limit Value	2 mg/m <sup>3</sup>
Latvia	0.5 mg/m <sup>3</sup>
Poland	STEL: 1 mg/m <sup>3</sup>
	0.5 mg/m <sup>3</sup>
Romania	1 mg/m <sup>3</sup>
	STEL: 3 mg/m <sup>3</sup>
Slovakia	2 mg/m <sup>3</sup>
Spain	STEL: 2 mg/m <sup>3</sup>
Switzerland	2 mg/m <sup>3</sup>
	STEL: 2 mg/m <sup>3</sup>
OSHA PEL	2 mg/m <sup>3</sup>
	(vacated) Ceiling: 2 mg/m <sup>3</sup>
United Kingdom	STEL: 2 mg/m <sup>3</sup>

## + Sulfuric acid

ACGIH TLV	0.2 mg/m <sup>3</sup>
Austria	0.1 mg/m <sup>3</sup>
	STEL 0.2 mg/m <sup>3</sup>
Bulgaria	0.05 mg/m <sup>3</sup>
Czech Republic	1 mg/m <sup>3</sup>
	0.05 mg/m <sup>3</sup>
	Ceiling: 2 mg/m <sup>3</sup>
Denmark	0.05 mg/m <sup>3</sup>
Estonia	0.05 mg/m <sup>3</sup>
European Union	TWA: 0.05 mg/m <sup>3</sup>
Finland	0.05 mg/m <sup>3</sup>
	STEL: 0.1 mg/m <sup>3</sup>
France	0.05 mg/m <sup>3</sup>
Germany	0.1 mg/m <sup>3</sup>
	Ceiling / Peak: 0.1 mg/m <sup>3</sup>
Germany	0.1 mg/m <sup>3</sup>
Hungary	0.05 mg/m <sup>3</sup>
Ireland	0.05 ppm
	STEL: 0.15 ppm
Italy	0.05 mg/m <sup>3</sup>
Ceiling Limit Value	1 mg/m <sup>3</sup>
Latvia	0.05 mg/m <sup>3</sup>
Netherlands	0.05 mg/m <sup>3</sup>
Poland	0.05 mg/m <sup>3</sup>
Romania	0.05 mg/m <sup>3</sup>
Russia	MAC: 1 mg/m <sup>3</sup>
	Skin
Slovakia	0.05 mg/m <sup>3</sup>
Spain	0.05 mg/m <sup>3</sup>
Switzerland	0.1 mg/m <sup>3</sup>

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
Revision date 16-Aug-2022

Page 6 / 12  
Version 1.01

OSHA PEL

United Kingdom

STEL: 0.2 mg/m<sup>3</sup>  
1 mg/m<sup>3</sup>  
(vacated) TWA: 1 mg/m<sup>3</sup>  
TWA: 0.05 mg/m<sup>3</sup>  
STEL: 0.15 mg/m<sup>3</sup>

## Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

## 8.2. 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.

### Environmental exposure controls

No information available.

### Personal protective equipment

Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

### Eye/face protection

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.).

### Hand protection

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.).

### Skin and body protection

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.).

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

#### Physical state

Liquid

#### Color

Colorless

#### Odor

No information available.

#### Odor threshold

No information available

#### Molecular formula

Mixture

#### Molecular weight

Mixture

#### Property

#### Values

#### pH

4.2 (3.0-6.5)

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
Revision date 16-Aug-2022

Page 7 / 12  
Version 1.01

<b>Melting point / freezing point</b>	No data available
<b>Boiling point / boiling range</b>	
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No data available
<b>Lower flammability limit:</b>	No data available
<b>Vapor pressure</b>	No data available
<b>Vapor density</b>	No data available
<b>Relative density</b>	No data available
<b>Water solubility</b>	Soluble
<b>Solubility(ies)</b>	No data available
<b>Partition coefficient</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	No data available
<b>Kinematic viscosity</b>	No data available
<b>Dynamic viscosity</b>	No data available
<b>Particle characteristics</b>	
<b>Particle Size</b>	No information available
<b>Particle Size Distribution</b>	No information available
<b>Explosive properties</b>	No information available

## 9.2. Other information

No information available

### 9.2.1. Information with regard to physical hazard classes

No information available

#### **Oxidizing properties**

None

### 9.2.2. Other safety characteristics

No information available

## **Section 10: STABILITY AND REACTIVITY**

### 10.1. Reactivity

**Reactivity** No data available.

### 10.2. Chemical stability

**Stability** Stable under normal conditions.

#### **Explosion data**

**Sensitivity to Mechanical Impact** No data available.

**Sensitivity to Static Discharge** No data available.

### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** No information available.

**Hazardous polymerization** Will not occur.

### 10.4. Conditions to avoid

**Conditions to avoid** Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

**Incompatible materials** None.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** Thermal decomposition products include oxides of carbon, nitrogen, and sulfur.

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
Revision date 16-Aug-2022

Page 8 / 12  
Version 1.01

## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

<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.
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

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

##### SODIUM CHLORIDE

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

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

##### + Sulfuric acid

Rat Oral LD50 2140 mg/kg

##### Sodium hydroxide

Mouse IP LD50 40 mg/kg

##### Atropine sulfate, monohydrate

Rat Oral LD50 500-600 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
SODIUM CHLORIDE	= 3 g/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h
Sodium hydroxide	= 325 mg/kg ( Rat )	= 1350 mg/kg ( Rabbit )	-
+ Sulfuric acid	= 2140 mg/kg ( Rat )	-	= 0.375 mg/L ( Rat ) 4 h

**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 irritation Rabbit Mild

Eye irritation Rabbit Mild

##### + Sulfuric acid

Eye Irritation Rabbit Severe

##### Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Atropine sulfate, monohydrate

100 Day(s) Rabbit Intramuscular 44 mg/kg/day LOAEL Male reproductive system, Gallbladder

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
Revision date 16-Aug-2022

Page 9 / 12  
Version 1.01

## Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Atropine sulfate, monohydrate

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  
Reproductive & Fertility Rat Oral 62.5 mg/kg NOAEL Fertility  
Embryo / Fetal Development Mouse Subcutaneous 50 mg/kg LOEL Fetotoxicity

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

### Atropine sulfate, monohydrate

Bacterial Mutagenicity (Ames) *Salmonella* Negative

## Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Atropine sulfate, monohydrate

2 Year(s) Rat Intraperitoneal Not carcinogenic

### Carcinogenicity

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

IARC  
NTP

Group 1 (Carcinogenic to Humans)  
Known Human Carcinogen

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 11.2.2. Other information

**Other adverse effects** No information available.

## Section 12: ECOLOGICAL INFORMATION

### **Environmental Overview:**

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

### 12.1. Toxicity

### 12.2. Persistence and degradability

**Persistence and degradability** No information available.

### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

### 12.4. Mobility in soil

**Mobility in soil** No information available.

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
Revision date 16-Aug-2022

Page 10 / 12  
Version 1.01

## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** No information available.

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
+ Sulfuric acid	The substance is not PBT / vPvB PBT assessment does not apply

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

## 12.7. Other adverse effects

No information available.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. 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 wastewater 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.

## Section 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.**

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable  
**Special precautions for user:** Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water  
**CERCLA/SARA Section 313 de minimus %** Not Listed  
**California Proposition 65** Not Listed  
**TSCA** Present

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
 Revision date 16-Aug-2022

Page 11 / 12  
 Version 1.01

<b>EINECS</b>	231-791-2
<b>AICS</b>	Present
<b>SODIUM CHLORIDE</b>	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	231-598-3
<b>AICS</b>	Present
<b>Sodium hydroxide</b>	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	215-185-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5 Schedule 6
<b>+ Sulfuric acid</b>	
<b>CERCLA/SARA Section 313 de minimus %</b>	1.0 %
<b>Hazardous Substances RQs</b>	1000 lb
<b>California Proposition 65</b>	carcinogen 3/14/2003
<b>TSCA</b>	Present
<b>EINECS</b>	231-639-5
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 6
<b>Atropine sulfate, monohydrate</b>	
<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Listed
<b>EINECS</b>	Not Listed
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 2 Schedule 4

Chemical name	French RG number	Title
SODIUM CHLORIDE 7647-14-5	RG 78	-

### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide - 1310-73-2	Use restricted. See item 75.	
+ Sulfuric acid - 7664-93-9	Use restricted. See item 75.	

### Persistent Organic Pollutants

Not applicable

### Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

# SAFETY DATA SHEET

Product Name Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)  
Revision date 16-Aug-2022

Page 12 / 12  
Version 1.01

## Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## **Section 16: OTHER INFORMATION**

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### **Full text of H-Statements referred to under 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 Reproductive toxicity-Cat.2; H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child

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

**Reason for revision** Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 16 - Other Information.

**Revision date** 16-Aug-2022

**Prepared By** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

**Pfizer Inc believes that the information contained in this 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.**