



A Pfizer Company

SAFETY DATA SHEET

Revision date: 03-Jan-2017

Version: 1.0

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

Product Identifier

Material Name: Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)

Trade Name: Atropine Sulfate Injection, USP
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as Anticholinergic agent

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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.

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

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

PZ03250

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
SODIUM CHLORIDE	7647-14-5	231-598-3	Not Listed	*
SODIUM HYDROXIDE	1310-73-2	215-185-5	Skin Corr. 1A (H314)	**
Atropine sulfate, monohydrate	5908-99-6	200-235-0	Acute Tox. 2 (H300) Acute Tox. 2 (H330)	0.005
Sulfuric acid	7664-93-9	231-639-5	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*

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.

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 Aggravated by Exposure:

None known

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

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Fire / Explosion Hazards: Not applicable

Advice for Fire-Fighters

During all fire fighting 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.

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 ³
Lithuania OEL - TWA	5 mg/m ³

SODIUM HYDROXIDE

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

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Latvia OEL - TWA	0.5 mg/m ³
OSHA - Final PELS - TWAs:	2 mg/m ³
Poland OEL - TWA	0.5 mg/m ³
Slovakia OEL - TWA	2 mg/m ³
Slovenia OEL - TWA	2 mg/m ³
Sweden OEL - TWAs	1 mg/m ³
Switzerland OEL -TWAs	2 mg/m ³

Atropine sulfate, monohydrate

Pfizer OEL TWA-8 Hr:	4µg/m ³
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Sulfuric acid

ACGIH Threshold Limit Value (TWA)	0.2 mg/m ³
Australia STEL	3 mg/m ³
Australia TWA	1 mg/m ³
Austria OEL - MAKs	0.1 mg/m ³
Belgium OEL - TWA	0.2 mg/m ³
Bulgaria OEL - TWA	0.05 mg/m ³
Cyprus OEL - TWA	0.05 mg/m ³
Czech Republic OEL - TWA	1 mg/m ³
	0.05 mg/m ³
Denmark OEL - TWA	0.05 mg/m ³
Estonia OEL - TWA	1 mg/m ³
Finland OEL - TWA	0.05 mg/m ³
France OEL - TWA	0.05 mg/m ³
Germany - TRGS 900 - TWAs	0.1 mg/m ³
Germany (DFG) - MAK	0.1 mg/m ³
Greece OEL - TWA	0.05 mg/m ³
Hungary OEL - TWA	0.05 mg/m ³
Ireland OEL - TWAs	0.05 ppm
Italy OEL - TWA	0.05 mg/m ³
Japan - OELs - Ceilings	1 mg/m ³
Latvia OEL - TWA	0.05 mg/m ³
Lithuania OEL - TWA	0.05 mg/m ³
Luxembourg OEL - TWA	0.05 mg/m ³
Malta OEL - TWA	0.05 mg/m ³
Netherlands OEL - TWA	0.05 mg/m ³
OSHA - Final PELS - TWAs:	1 mg/m ³
Poland OEL - TWA	0.05 mg/m ³
Portugal OEL - TWA	0.05 mg/m ³
Romania OEL - TWA	0.05 mg/m ³
Slovakia OEL - TWA	0.1 mg/m ³
Slovenia OEL - TWA	0.05 mg/m ³
Spain OEL - TWA	0.05 mg/m ³
Sweden OEL - TWAs	0.1 mg/m ³
Switzerland OEL -TWAs	0.1 mg/m ³
Vietnam OEL - TWAs	1 mg/m ³

SODIUM CHLORIDE

Pfizer Occupational Exposure OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)
 Band (OEB):

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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.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Colorless
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	Soluble		
pH:	4.2 (3.0-6.5)		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
SODIUM HYDROXIDE			
No data available			
SODIUM CHLORIDE			
No data available			
Sulfuric acid			
No data available			
Atropine sulfate, monohydrate			
No data available			
Water for Injection			
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	

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Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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)

SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m³
Rat Oral LD 50 3g/kg
Mouse Oral LD 50 4g/kg
Rabbit Dermal LD 50 > 10g/kg

Sulfuric acid

Rat Oral LD50 2140 mg/kg

Atropine sulfate, monohydrate

Rat Oral LD50 500-600 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 Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Sulfuric acid

Eye Irritation Rabbit Severe

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

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11. TOXICOLOGICAL INFORMATION

Atropine sulfate, monohydrate

Embryo / Fetal Development Oral50 mg/kg LOAEL 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

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.

14. TRANSPORT INFORMATION

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

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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

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

Water for Injection

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

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
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 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Atropine sulfate, monohydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	200-235-0

Sulfuric acid

CERCLA/SARA 313 Emission reporting	1.0 %
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15. REGULATORY INFORMATION

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

Additional Information: EU labeling prescribed by Annex 1

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: 03-Jan-2017

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc 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