SAFETY DATA SHEET

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

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
3. COMPOSITION / INFORMATION ON INGREDIENTS

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

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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Material Name: Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)
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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/m³
Lithuania OEL - TWA 5 mg/m³

SODIUM HYDROXIDE
ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK 2 mg/m³
Austria OEL - MAKs 2 mg/m³
Bulgaria OEL - TWA 2.0 mg/m³
Czech Republic OEL - TWA 1 mg/m³
Estonia OEL - TWA 1 mg/m³
France OEL - TWA 2 mg/m³
Greece OEL - TWA 2 mg/m³
Hungary OEL - TWA 2 mg/m³
Japan - OELs - Ceilings 2 mg/m³
Atropine sulfate, monohydrate

Pfizer OEL TWA-8 Hr:

4µg/m³

Sulfuric acid

ACGIH Threshold Limit Value (TWA) 0.2 mg/m³
Australia STEL 3 mg/m³
Australia TWA 1 mg/m³
Austria OEL - MAKs 0.1 mg/m³
Belgium OEL - TWA 0.2 mg/m³
Bulgaria OEL - TWA 0.05 mg/m³
Cyprus OEL - TWA 0.05 mg/m³
Czech Republic OEL - TWA 1 mg/m³

0.05 mg/m³
Denmark OEL - TWA
Estonia OEL - TWA 1 mg/m³
Finland OEL - TWA 0.05 mg/m³
France OEL - TWA 0.05 mg/m³
Germany - TRGS 900 - TWAs 0.1 mg/m³
Germany (DFG) - MAK 0.1 mg/m³

0.05 mg/m³
Greek OEL - TWA
Hungary OEL - TWA 0.05 mg/m³
Ireland OEL - TWAs 0.05 ppm
Italy OEL - TWA 0.05 mg/m³
Japan - OELs - Ceilings 1 mg/m³
Latvia OEL - TWA 0.05 mg/m³
Lithuania OEL - TWA 0.05 mg/m³
Luxembourg OEL - TWA 0.05 mg/m³
Malta OEL - TWA 0.05 mg/m³

0.05 mg/m³
Netherlands OEL - TWA
OSH A - Final PELS - TWAs: 1 mg/m³
Poland OEL - TWA 0.05 mg/m³
Portugal OEL - TWA 0.05 mg/m³
Romania OEL - TWA 0.05 mg/m³
Slovakia OEL - TWA 0.1 mg/m³
Slovenia OEL - TWA 0.05 mg/m³
Spain OEL - TWA 0.05 mg/m³

0.1 mg/m³
Sweden OEL - TWAs
Switzerland OEL - TWAs 0.1 mg/m³
Vietnam OEL - TWAs 1 mg/m³

SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)
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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
<th>Color:</th>
<th>Colorless</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
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<td>Boiling Point (°C):</td>
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<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
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</tr>
<tr>
<td>SODIUM HYDROXIDE</td>
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<tr>
<td>SODIUM CHLORIDE</td>
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</tr>
<tr>
<td>Sulfuric acid</td>
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<tr>
<td>Atropine sulfate, monohydrate</td>
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<tr>
<td>Water for Injection</td>
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<td>Decomposition Temperature (°C):</td>
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<td>Vapor Density (g/ml):</td>
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<td>Flash Point (Liquid) (°C):</td>
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</tbody>
</table>
SAFETY DATA SHEET

Material Name: Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)
Revision date: 03-Jan-2017

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))
11. TOXICOLOGICAL INFORMATION

Atropine sulfate, monohydrate

<table>
<thead>
<tr>
<th>Embryo / Fetal Development</th>
<th>Oral50 mg/kg</th>
<th>LOAEL</th>
<th>Developmental toxicity, Maternal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rat</td>
<td>Not Teratogenic</td>
<td></td>
</tr>
<tr>
<td>Embryo / Fetal Development</td>
<td>Dog</td>
<td>LOEL</td>
<td>Not Teratogenic</td>
</tr>
</tbody>
</table>

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.
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
- 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
- EU EINECS/ELINCS List: 215-185-5

Atropine sulfate, monohydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: 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 %
SAFETY DATA SHEET

Material Name: Atropine Sulfate Injection, USP (Pediatric) (Hospira Inc.)
Revision date: 03-Jan-2017

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</th>
<th>1000 lb</th>
</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA - Section 302 Extremely Hazardous EPCRA RQs</td>
<td>454 kg</td>
</tr>
<tr>
<td>California Proposition 65</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<td>Australia (AICS):</td>
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<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 6</td>
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<tr>
<td>EU EINECS/ELINCS List</td>
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</table>

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 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