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

Product Identifier
- Material Name: EPHEDRINE SULFATE INJECTION, USP
- Trade Name: Not established
- Chemical Family: Phenethylamine derivative

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
- Intended Use: Pharmaceutical product

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
- International Chemtrec (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

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

Hazardous

PZ03754
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>
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</thead>
<tbody>
<tr>
<td>Ephedrine sulfate</td>
<td>134-72-5</td>
<td>205-154-4</td>
<td>Acute Tox. 4 (H302)</td>
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</tbody>
</table>

<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>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed*</td>
<td></td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary 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:**
Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

**Skin Contact:**
Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**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:**
Use carbon dioxide, dry chemical, or water spray.

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

**Hazardous Combustion Products:**
Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

**Fire / Explosion Hazards:**
Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters:**
Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.
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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

**Precautions for Safe Handling**
Avoid breathing vapor or mist. 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.
- **Specific end use(s):** Pharmaceutical product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

**Ephedrine sulfate**

- **Pfizer OEL TWA-8 Hr:** 200µg/m³

**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). 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.

- **Hands:** Impervious gloves (e.g. Nitrile, etc.) are 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 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.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Solution</th>
<th>Color:</th>
<th>Clear, colorless</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
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<td>Odor Threshold:</td>
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</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Water Solubility:</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water for Injection</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Ephedrine sulfate</td>
<td>No data available</td>
<td></td>
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</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
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<td></td>
<td></td>
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<tr>
<td>Vapor Pressure (kPa):</td>
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<tr>
<td>Vapor Density (g/ml):</td>
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<tr>
<td>Relative Density:</td>
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<td></td>
</tr>
<tr>
<td>Viscosity:</td>
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<td></td>
</tr>
</tbody>
</table>

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

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable
Possibility of Hazardous Reactions
- Oxidizing Properties: No data available
- Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The following information is available for the individual ingredients.
11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including chest pain, chills or fever, increased sweating, convulsions, dizziness, rapid, pounding, or irregular heart rhythm, hallucinations, headache, high or low blood pressure, nausea, or vomiting, troubled breathing, trembling, restlessness, or anxiety, blurred vision, difficult or painful urination, troubled sleeping, and weakness. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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

Ephedrine sulfate
Mouse  Oral  LD50  812 mg/kg
Rat  Oral  LD50  404mg/kg

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

Ephedrine sulfate
13 Week(s)  Rat  Oral, in feed  2000 ppm  NOAEL  None identified
13 Week(s)  Mouse  Oral, in feed  5000 ppm  NOAEL  None identified

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

Ephedrine sulfate
Bacterial Mutagenicity (Ames)  Negative
Sister Chromatid Exchange  Chinese Hamster Ovary (CHO) cells  Negative
Chromosome Aberration  Chinese Hamster Ovary (CHO) cells  Negative

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

Ephedrine sulfate
2 Year(s)  Rat  Oral, in feed  250 ppm  NOAEL  Not carcinogenic
2 Year(s)  Mouse  Oral, in feed  250 ppm  NOAEL  Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been 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

Ephedrine sulfate
- 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: 205-154-4

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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: New data sheet.

Revision date: 21-Jun-2019

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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet