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

Product Identifier

Material Name: Alfentanil Injection, USP (Hospira Inc.)

Trade Name: Alfentanil Injection, USP
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as analgesic, anesthetic 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

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

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

<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>Alfentanil Hydrochloride</td>
<td>69049-06-5</td>
<td>273-846-3</td>
<td>Acute Tox 3 (H301)(H361fd)</td>
<td>&lt;0.1</td>
</tr>
</tbody>
</table>

PZ03072
SAFETY DATA SHEET

Material Name: Alfentanil Injection, USP (Hospira Inc.)  
Revision date: 25-Jul-2016

<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>
<tr>
<td>SODIUM CHLORIDE</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>&lt;1</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: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

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: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

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
SAFETY DATA SHEET

Material Name: Alfentanil Injection, USP (Hospira Inc.)
Revision date: 25-Jul-2016
Version: 1.0

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 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 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

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.

Alfentanil Hydrochloride

Pfizer Occupational Exposure Band (OEB):
OEB 4 - Skin (control exposure to the range of 1ug/m³ to <10ug/m³, provide additional precautions to protect from skin contact)

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.)
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 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>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Solution</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available.</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available.</td>
</tr>
<tr>
<td>pH</td>
<td>4-6</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>No data available.</td>
</tr>
<tr>
<td>SODIUM CHLORIDE</td>
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</tr>
<tr>
<td>Alfentanil Hydrochloride</td>
<td>No data available.</td>
</tr>
<tr>
<td>Decomposition Temperature (°C)</td>
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</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
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</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
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</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available.</td>
</tr>
<tr>
<td>Relative Density</td>
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</tr>
<tr>
<td>Viscosity</td>
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</tr>
<tr>
<td>Flammability:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Flammability (Solids):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available.</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

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: Not determined
- Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
- Hazardous Decomposition: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May be absorbed through the skin and cause systemic effects. Use of this drug is habit forming. Addiction may occur.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

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, hypotension, coma, convulsions, cardiac arrhythmia, and tachycardia.

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

Alfentanil Hydrochloride
- Rat Intravenous LD50 43-51 mg/kg
- Mouse IV LD50 72-74mg/kg
- Guinea Pig Intravenous LD50 72-82mg/kg
- Dog Intravenous LD50 60-88mg/kg

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

SODIUM CHLORIDE
- Skin Irritation Rabbit Mild
- Eye Irritation Rabbit Mild

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

Alfentanil Hydrochloride
- Embryo / Fetal Development Rat Intravenous 1.25 mg/kg/day LOEL Embryotoxicity, Not teratogenic
- Embryo / Fetal Development Rabbit Intravenous 1.25 mg/kg/day LOEL Embryotoxicity, Not Teratogenic

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

Alfentanil Hydrochloride
- Bacterial Mutagenicity (Ames) Salmonella Negative
- In Vivo Micronucleus Rat Negative
- In Vivo Dominant Lethal Assay Mouse Negative

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 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

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:
  - EU EINECS/ELINCS List: 231-791-2

Alfentanil Hydrochloride
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: 273-846-3

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15. REGULATORY INFORMATION

SODIUM CHLORIDE

<table>
<thead>
<tr>
<th>Data Source</th>
<th>Information</th>
</tr>
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<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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<td>California Proposition 65</td>
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</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>231-598-3</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Reproductive toxicity-Cat.2; H361fd - Suspected of damaging fertility. Suspected of damaging the unborn child.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Revision date: 25-Jul-2016

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