MATERIAL SAFETY DATA SHEET

Product Name: Alfentanil Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency 224-212-2000

Product Name
Alfentanil Injection, USP

Synonyms
N-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl]-4-(methoxymethyl)-4-piperidinyl]-N-phenylpropanamide monohydrochloride (1:1)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Alfentanil Hydrochloride

Chemical Formula
C_{21}H_{32}N_{6}O_{3} \cdot HCl

Preparation
Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfentanil Hydrochloride</td>
<td>0.05</td>
<td>69049-06-5</td>
<td>TX1452500</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfentanil Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Alfentanil Injection, USP contains alfentanil hydrochloride, a short-acting opioid analgesic. Clinically, it is used as an analgesic and anesthetic during surgery. Alfentanil is about 25 times more potent than morphine and about 1/4 as potent as fentanyl. Alfentanil is a U.S. Schedule II Controlled Drug Substance; it can produce drug dependence and has the potential to be abused. In the workplace, this material should be considered a potent drug and potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the central nervous system, cardiovascular system, gastrointestinal system, respiratory system and the musculoskeletal system.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. However, this material may be absorbed through skin. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposure. In clinical use, the most frequent adverse effects
include respiratory depression and skeletal muscle rigidity. Other adverse effects may include bradycardia, arrhythmias, hypotension, gastrointestinal disturbances, dizziness, sleepiness, blurred vision, laryngospasm, bronchospasm, headache, shivering, urticaria and itching. Overdose produces symptoms that are an extension or exaggeration of the expected pharmacological effects of alfentanil.

Medical Conditions Aggravated by Exposure

Hypersensitivity to alfentanil or related compounds; pre-existing respiratory, central nervous system, skeletal muscle, or cardiovascular system ailments.

4. FIRST AID MEASURES

**Eye contact**
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin contact**
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Inhalation**
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion**
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Naloxone can be used as an antidote to reverse respiratory depression.

5. FIRE FIGHTING MEASURES

**Flammability**
None anticipated for this aqueous product.

**Fire & Explosion Hazard**
None anticipated for this aqueous product.

**Extinguishing media**
As with any fire, use extinguishing media appropriate for primary cause of fire.

**Special Fire Fighting Procedures**
No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

**Spill Cleanup and Disposal**
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

**Handling**
No special handling required for hazard control under conditions of normal product use. In the United States, alfentanil is a Schedule II controlled substance. Appropriate training and procedures may be required during the routine handling of this product.

**Storage**
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
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Special Precautions

No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfentanil Hydrochloride</td>
<td>Hospira EEL</td>
<td>N/A</td>
<td>N/A</td>
<td>1</td>
<td>8hr TWA, Skin</td>
</tr>
</tbody>
</table>

Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N99 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

- Appearance/Physical State: Liquid
- Color: Sterile, non-pyrogenic, preservative free aqueous solution.
- Odor: NA
- Odor Threshold: NA
- pH: 4.0 to 6.0
- Melting point/Freezing point: NA
- Initial Boiling Point/Boiling Point Range: NA
- Evaporation Rate: NA
- Flammability (solid, gas): NA
- Upper/Lower Flammability or Explosive Limits: NA
- Vapor Pressure: NA
- Vapor Density: NA
- Specific Gravity: NA
- Solubility: NA
- Partition coefficient: n-octanol/water: 128:1 at pH 7.4
- Auto-ignition temperature: NA
- Decomposition temperature: NA
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10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Not determined.

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and hydrogen chloride.

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
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<tbody>
<tr>
<td>Alfentanil Hydrochloride</td>
<td>100%</td>
<td>LD50</td>
<td>Intravenous</td>
<td>Intravenous</td>
<td>47.5</td>
<td>mg/kg</td>
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<td></td>
<td></td>
<td>43-51</td>
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<td></td>
<td></td>
<td>72-74</td>
<td>mg/kg</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td>72-82</td>
<td>mg/kg</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>60-88</td>
<td>mg/kg</td>
</tr>
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</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. In clinical use, a small percentage of patients (generally less than 1%) experience dermatological reactions including itching and urticaria.

Reproductive Effects
Alfentanil was embryocidal in rats and rabbits receiving 2.5 times the maximum human dose for 10 to 30 days. Maternal toxicity probably contributed to the embryotoxic effects observed. No evidence of teratogenicity was observed. FDA Pregnancy Category C.

Mutagenicity
No structural chromosome mutations were produced in the in vivo micronucleus test in female rats at single intravenous doses of alfentanil as high as 20 mg/kg body weight, equivalent to a dose of 103 mg/m2 body surface area. No dominant lethal mutations were produced in the in vivo dominant lethal test in male and female mice at the maximum intravenous dose.
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Carcinogenicity
No long-term animal studies of alfentanil have been performed to evaluate carcinogenic potential.

Target Organ Effects
Based on clinical use, possible target organs include the central nervous system, cardiovascular system, gastrointestinal system, respiratory system and the musculoskeletal system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product.

Persistence/Biodegradability
Not determined for product.

Bioaccumulation
Not determined for product.

Mobility in Soil
Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal
In the United States, alfentanil is a Schedule II controlled substance. All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated
IMDG STATUS: Not regulated
ICAO/IATA STATUS: Not regulated
Transport Comments: None
15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfentanil Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<td>Not Listed</td>
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</tr>
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</table>

RCRA Status: Not Listed
U.S. OSHA Classification:
- Possibly Toxic by Ingestion
- Target Organ Toxin
- Possible Irritant

GHS Classification:
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.*

Hazard Class: Not Applicable
Hazard Category: Not Applicable
Signal Word: Not Applicable
Symbol: Not Applicable
Hazard Statement: Not Applicable
Response:
IFE IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.
Get medical attention if you feel unwell.

EU Classification*
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Alfentanil Hydrochloride.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases:
- S23 - Do not breathe vapor.
- S24/25 - Avoid contact with skin and eyes.
- S37/39 - Wear suitable gloves and eye/face protection.
## 16. OTHER INFORMATION:

<table>
<thead>
<tr>
<th>Notes:</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
<td>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
</tr>
<tr>
<td>EEL</td>
<td>Employee Exposure Limit</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>LD50</td>
<td>Dosage producing 50% mortality</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable/Not available</td>
</tr>
<tr>
<td>NE</td>
<td>Not established</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
</tr>
<tr>
<td>Prop 65</td>
<td>California Proposition 65</td>
</tr>
<tr>
<td>RCRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
</tr>
<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
</tr>
</tbody>
</table>

**MSDS Coordinator:** Hospira GEHS  
**Date Prepared:** 08/29/2011  
**Obsolete Date:** 10/21/2008

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