MATERIAL SAFETY DATA SHEET

Product Name: Sufentanil Citrate 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
Sufentanil Citrate Injection, USP

Synonyms
N-[4-(methyoxymethyl)-1-[2-(2-thienyl)ethyl]-4-piperidinyl]-N-
phenylpropanamide 2-hydroxy-1,2,3-propanetricarboxylate (1:1)

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Sufentanil Citrate

Chemical Formula
C₂₂H₃₀N₂O₅S•C₆H₈O₇

Preparation
Non-hazardous ingredients include Water for Injection. Sodium hydroxide and/or hydrochloric acid may be use to adjust the pH.

<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>Sufentanil Citrate</td>
<td>0.005</td>
<td>60561-17-3</td>
<td>UE5295000</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>Sufentanil Citrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Sufentanil Citrate Injection, USP is a solution containing sufentanil citrate, a potent analgesic (pain reliever) used as an adjunct to anesthesia, and as a primary anesthetic drug in procedures requiring assisted ventilation. Sufentanil Citrate Injection is a Schedule II controlled drug substance that can produce drug dependence of the morphine type and therefore has the potential for being abused. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract, a potent drug, and a potential occupational reproductive hazard. Based on clinical use, possible target organs include the central nervous system, respiratory system, cardiovascular system, and possibly the fetus.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposure. In clinical use, the most common adverse reactions are respiratory depression, skeletal muscle rigidity, and drowsiness. Less frequently,
bradycardia, hypotension/hypertension, and chest wall rigidity may occur. Other adverse effects occurring in

**Medical Conditions Aggravated by Exposure**

Pre-existing hypersensitivity to the material and/or similar materials. Pre-existing central nervous system, cardiovascular system and respiratory 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, an opiate antagonist, can be used as a specific 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. Sufentanil Citrate Injection is a Schedule II controlled drug substance that can produce drug dependence of the morphine type and therefore has the potential for being abused. Additional procedures and training may be required when handling a controlled substance.

**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.
Special Precautions
No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<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>Sufentanil Citrate</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</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 (N95 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>Sterile, nonpyrogenic solution</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH:</td>
<td>NA</td>
</tr>
<tr>
<td>Melting point/Freezing point:</td>
<td>4.2 (3.5 to 6.0)</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>0.9961 g/ml at 25°C</td>
</tr>
<tr>
<td>Solubility:</td>
<td>NA</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
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
Strong acids, oxidants

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 sulfur oxides (SOx).

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>
</tr>
</thead>
<tbody>
<tr>
<td>Sufentanil Citrate</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>17.9</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>18.7</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>11.8, 13.0</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>14.1, 10.1, 19.5</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
</tbody>
</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.

Reproductive Effects
Reproduction studies performed in rats and rabbits given doses of up to 2.5 times the upper human intravenous dose for a period of 10 to over 30 days revealed high maternal mortality rates due to decreased food consumption and anoxia, which preclude any meaningful interpretation of the results. Sufentanil has been shown to have an embryocidal effect in rats and rabbits when given in doses 2.5 times the upper human intravenous dose for a period of 10 days to over 30 days. These effects may be due to maternal toxicity (decreased food consumption with increased mortality) following prolonged administration of the drug.

Mutagenicity
The micronucleus test in female rats revealed that single intravenous doses of sufentanil as high as 80 mcg/kg produced no structural chromosome mutations. The Ames *Salmonella typhimurium* metabolic activating test also revealed no
Product Name: Sufentanil Citrate Injection, USP

mutagenic activity.

Carcinogenicity  No long-term animal studies of sufentanil have been performed to evaluate carcinogenic potential.

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

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  All waste materials must be properly characterized. Sufentanil Citrate Injection is a Schedule II controlled drug substance and may have additional requirements for proper disposal. 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>Sufentanil Citrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>


Product Name: Sufentanil Citrate Injection, USP

**RCRA Status** 
Not Listed

**U.S. OSHA Classification** 
Target Organ Toxin
Possible Reproductive 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

**Prevention** 
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.

**Hazard Statement** 
Not Applicable

**Response:** 
IF 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 Sufentanil Citrate.

**Classification(s):** 
Not Applicable

**Symbol:** 
Not Applicable

**Indication of Danger:** 
Not Applicable

**Risk Phrases:** 
Not Applicable

**Safety Phrases:** 
S23 - Do not breathe vapor.
S24 - Avoid contact with skin.
S25 - Avoid contact with eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

**Notes:**
- ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value
- CAS: Chemical Abstracts Service Number
- CERCLA: US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
- DOT: US Department of Transportation Regulations
- EEL: Employee Exposure Limit
- IATA: International Air Transport Association
- LD50: Dosage producing 50% mortality
- NA: Not applicable/Not available
Product Name: Sufentanil Citrate Injection, USP

NE Not established
NIOSH National Institute for Occupational Safety and Health
OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65 California Proposition 65
RCRA US EPA, Resource Conservation and Recovery Act
RTECS Registry of Toxic Effects of Chemical Substances
SARA Superfund Amendments and Reauthorization Act
STEL 15-minute Short Term Exposure Limit
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 11/03/2011
Obsolete Date: 10/21/2008

Disclaimer:
The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.