



## MATERIAL SAFETY DATA SHEET

**Product Name: Fentanyl Citrate Injection, USP** 

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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

**Note:** Hospira, formerly the Hospital Products Division of Abbott Laboratories, was created as an independent company in May 2004.

**Emergency Telephone  
Hospira, Inc.** CHEMTREC: 800 424-9300  
224 212-2055

**Product Name** Fentanyl Citrate Injection, USP

**Synonyms** None

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Ingredient Name** Fentanyl Citrate  
**Chemical Formula**  $C_{28}H_{36}N_2O_8$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Fentanyl Citrate	0.005	990-73-8	UE5550000
Water	99	7732-18-5	ZC0110000

### 3. HAZARD INFORMATION

**Emergency Overview** In clinical use, this material is used to relieve pain and produce sedation. Possible target organs include the skin, ears, fetus, eyes, lungs, central nervous system and cardiovascular system.

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

**Signs and Symptoms** No signs or symptoms from occupational exposure are known. Clinical data suggest the following: respiratory depression, slow heart rate, muscle weakness, altered blood pressure, dizziness, nausea, vomiting, sweating, euphoria, pinpoint pupils, breathing difficulty.

**Medical Conditions  
Aggravated by Exposure** Hypersensitivity to the material and/or similar materials. Pre-existing ailments in the following organs: respiratory system, liver, kidney, heart.

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**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.

**5. FIRE FIGHTING MEASURES**

**Flammability:** Non-flammable

**Fire & Explosion Hazard:** None

**Extinguishing Media:** 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** Absorb with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

**7. HANDLING AND STORAGE**

**Handling** Protect from light by retaining in carton until contents have been used.

**Storage** No special storage required for hazard control. For product protection store at controlled room temperature of 15-30°C (59-86°F).

**Special Precautions** Protect from freezing, light and extreme heat.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Exposure Guidelines**

Component	Exposure limits		
	OSHA-PEL	ACGIH-TLV	Hospira EEL
Fentanyl Citrate	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 0.1 mcg/m3 STEL: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
EEL: Employee Exposure Limit.  
TWA: 8 hour Time Weighted Average.  
STEL: 15-minute Short Term Exposure Limit.

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**Respiratory Protection**                      Respiratory protection is not needed during normal product use.

**Skin Protection**                              If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.

**Eye Protection**                              Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.

**Engineering Controls**                      Engineering controls are not needed during normal product use conditions.

**9. PHYSICAL/CHEMICAL PROPERTIES**

**Appearance/Physical State**                      Clear liquid

**Odor**    Not Determined

**Boiling Point**                                  Approximately that of water (100 °C, 212 °F).

**Freezing Point**                                Approximately that of water (0 °C, 32 °F).

**Vapor Pressure**                                Approximately that of water (17.5 mm Hg at 20 °C).

**Vapor Density (Air=1)**                        Not Applicable

**Evaporation Rate**                              Not Applicable

**Bulk Density**                                    Not Determined

**Specific Gravity**                                Approximately that of water (1.0)

**Solubility**                                        Aqueous solution

**pH**     4.0 – 7.5

**10. STABILITY AND REACTIVITY**

**Chemical Stability**                      Stable under standard use and storage conditions.

**Incompatibilities**                      None

**Hazardous Decomposition Products**                      Toxic fumes of nitrogen oxides.

**Hazardous Polymerization**                      Not Determined.

**11. TOXICOLOGICAL INFORMATION:**

**Acute Toxicity – Oral:**

<b>Ingredient(s)</b>	<b>Percent</b>	<b>Test Type</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
Fentanyl Citrate	100	LD50	18-136	mg/kg	Rats, Mice

LD50 is the dosage producing 50% mortality.  
Product contains less than 0.01% Fentanyl Citrate.

**Mutagenicity**                                  Not Determined

**Target Organ Effects**                      In clinical use target organ effects include nervous system, respiratory system, muscle, cardiovascular system, gastrointestinal tract, female reproductive system.

**12. ECOLOGICAL INFORMATION:**

**Aquatic Toxicity**                              Not Available

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### **13. DISPOSAL CONSIDERATIONS:**

<b>Waste Disposal</b>	Disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state, and local regulations.

### **14. TRANSPORTATION INFORMATION**

**DOT** Not Regulated

Notes: DOT - US Department of Transportation Regulations

### **15. REGULATORY INFORMATION**

<b>TSCA Status</b>	Not Regulated
<b>CERCLA Status</b>	Not Regulated
<b>SARA Status</b>	Not Regulated
<b>RCRA Status</b>	Not Regulated
<b>PROP 65 (Calif.)</b>	Not Regulated

Notes: TSCA Toxic Substance Control Act  
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act  
SARA Superfund Amendments and Reauthorization Act  
RCRA US EPA, Resource Conservation and Recovery Act  
Prop 65, California Proposition 65

### **16. OTHER INFORMATION:**

<b>MSDS Coordinator</b>	T. Straits MPH, CIH
<b>Date Prepared</b>	September 15, 2005

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