



# MATERIAL SAFETY DATA SHEET

Revision date: 23-Jan-2007

Version: 1.2

Page 1 of 5

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

**Pfizer Inc**  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

**Pfizer Ltd**  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Fentanyl Citrate Injectable Solution**

**Trade Name:** Fentanest  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as analgesic, anesthetic agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Fentanyl Citrate	990-73-8	213-588-0	<0.1

Ingredient	CAS Number	EU EINECS List	%
Propylparaben	94-13-3	202-307-7	*
Water for Injection	7732-18-5	231-791-2	*
Methylparaben	99-76-3	202-785-7	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** Solution

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

### Additional Hazard Information:

**Short Term:** May be absorbed through the skin and cause systemic effects. May be fatal if swallowed (based on components). 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. Animal studies indicate that this material may cause adverse effects on the reproductive system.

**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.

**EU Indication of danger:** Not classified

## MATERIAL SAFETY DATA SHEET

Material Name: Fentanyl Citrate Injectable Solution  
Revision date: 23-Jan-2007

Page 2 of 5  
Version: 1.2

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

### 4. 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 clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

**Ingestion:** Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

**Inhalation:** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

### 5. FIRE FIGHTING MEASURES

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

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

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Not applicable

### 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**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.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**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

**General Handling:** Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use with adequate ventilation.

**Storage Conditions:** Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

# MATERIAL SAFETY DATA SHEET

Material Name: Fentanyl Citrate Injectable Solution  
Revision date: 23-Jan-2007

Page 3 of 5  
Version: 1.2

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.

## Fentanyl Citrate

**Pfizer Occupational Exposure Band (OEB):** OEB5 - Skin (control exposure to <1ug/m<sup>3</sup>, provide additional precautions to protect from skin contact)

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

## Personal Protective Equipment:

**Hands:** Wear impervious gloves if skin contact is possible.  
**Eyes:** Safety glasses or goggles  
**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.  
**Respiratory protection:** If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

## 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Solution	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Not determined  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

## 11. TOXICOLOGICAL INFORMATION

**General Information:** There are no data for this formulation. The remaining information describes the potential hazards of the individual ingredients.

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

#### Fentanyl Citrate

Rat	Oral	LD50	18 mg/kg
Rat	Intravenous	LD50	990 ug/kg
Rat	Intraperitoneal	LD50	2070 ug/kg
Mouse	Oral	LD50	368 mg/kg
Mouse	Intravenous	LD50	10100 ug/kg

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

## MATERIAL SAFETY DATA SHEET

Material Name: Fentanyl Citrate Injectable Solution  
Revision date: 23-Jan-2007

Page 4 of 5  
Version: 1.2

### Fentanyl Citrate

Reproductive & Fertility	Rat	Subcutaneous	1.25 mg/kg/day	LOAEL	Fertility
Reproductive & Fertility	Rat	Intravenous	30 ug/kg	LOAEL	Fertility, Embryotoxicity
Reproductive & Fertility	Rat	Subcutaneous	160 ug/kg	LOAEL	Fertility, Embryotoxicity
Embryo / Fetal Development	Rat	Oral	500 ug/kg	NOAEL	Not Teratogenic

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

#### Fentanyl Citrate

Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
<i>In Vivo</i> Micronucleus	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.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

### OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

### Canada - WHMIS: Classifications

# MATERIAL SAFETY DATA SHEET

Material Name: Fentanyl Citrate Injectable Solution  
Revision date: 23-Jan-2007

Page 5 of 5  
Version: 1.2

## WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

## Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-307-7

## Water for Injection

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

## Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-785-7

## Fentanyl Citrate

Australia (AICS):	Present
EU EINECS List	213-588-0

## 16. OTHER INFORMATION

### Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

### Prepared by:

Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**