



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 2.1

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

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

### Material Name: Triptorelin Pamoate for Injection

**Trade Name:** Trelstar (R); Decapeptyl (R)  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product for the treatment of prostate cancer

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Triptorelin	57773-63-4	Not listed	4

Ingredient	CAS Number	EU EINECS List	%
Poly(dl-lactide-co-glycolide)	26780-50-7	Not listed	*
Mannitol	69-65-8	200-711-8	*
Polysorbate 80	9005-65-6	Not listed	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	*

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** White to slightly yellow (lyophilised) powder  
**Signal Word:** WARNING

**Statement of Hazard:** May cause reproductive system effects

### Additional Hazard Information:

**Short Term:** Toxicity following ingestion is not expected. However, ingestion should be avoided.  
**Long Term:** Adverse reproductive effects seen in repeat-dose animal studies are consistent with the pharmacologic action of this drug and are expected to be relevant to humans.

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include hot flushes, leg pain, nausea, diarrhea, insomnia, and headache. Can produce impotence and other sexual disturbances in men.

**EU Indication of danger:** Toxic to reproduction: Category 1

**EU Hazard Symbols:**

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### EU Risk Phrases:

R60 - May impair fertility.

### 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:** Flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
- Skin Contact:** Wash skin with soap and water. If irritation occurs or persists, get 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.

## 5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide and oxides of nitrogen
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

## 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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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:** Avoid breathing dust. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

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**Storage Conditions:** Store as directed by product packaging. Keep out of reach of children.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Personal Protective Equipment:**

**Hands:** Rubber gloves  
**Eyes:** Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.  
**Skin:** Controls must be implemented to avoid all skin contact with the material.  
**Respiratory protection:** Not required for the normal use of this product. If dust is present, a laboratory fume hood, local exhaust ventilation or an appropriate respirator should be used. The specific type used will be determined by air concentrations present. Follow local regulations for respirator use in the workplace.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Lyophilized powder	<b>Color:</b>	White to slightly yellow
<b>Odor:</b>	Odorless	<b>Molecular Formula:</b>	Mixture
<b>Molecular Weight:</b>	Mixture		

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

### 11. TOXICOLOGICAL INFORMATION

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

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

**Mannitol**

Rat Oral LD 50 13500 mg/kg  
Mouse Oral LD 50 22 g/kg

**Carboxymethylcellulose sodium**

Mouse Oral LD50 > 27,000 mg/kg  
Rat Oral LD50 27,000 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

**Polysorbate 80**

Rat Intravenous LD 50 1790 mg/kg  
Mouse Oral LD 50 25 g/kg

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**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

#### Carboxymethylcellulose sodium

13 Week(s) Rat Oral 227 g/kg LOEL Liver, Kidney, Ureter, Bladder

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

#### Triptorelin

Reproductive & Fertility Rat Subcutaneous 100 ug/kg LOEL Maternal toxicity, Embryotoxicity, Not teratogenic  
Embryo / Fetal Development Mouse No route specified 200 ug/kg/day NOEL Not Teratogenic

### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Triptorelin

6 Month(s) Rat Intramuscular 120 ug/kg/month LOEL Pituitary gland, Benign tumors  
18 Month(s) Mouse Intramuscular 6000 ug/kg/month NOEL Not carcinogenic

**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 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 Symbol:** T  
**EU Indication of danger:** Toxic to reproduction: Category 1

**EU Risk Phrases:** R60 - May impair fertility.

**EU Safety Phrases:**

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S22 - Do not breathe dust.  
S53 - Avoid exposure - obtain special instructions before use.  
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

## OSHA Label:

WARNING

May cause reproductive system effects

## Canada - WHMIS: Classifications

### WHMIS hazard class:

Class D, Division 2, Subdivision A



### Triptorelin

Standard for the Uniform Scheduling  
for Drugs and Poisons:

Schedule 4

### Mannitol

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

Present  
Present  
200-711-8

### Polysorbate 80

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):

XU  
Present

### Carboxymethylcellulose sodium

Inventory - United States TSCA - Sect. 8(b)  
Australia (AICS):

XU  
Present

## 16. OTHER INFORMATION

### Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 11 - Toxicology Information.  
Updated Section 13 - Disposal Considerations.

### Prepared by:

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

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**End of Safety Data Sheet**