



# MATERIAL SAFETY DATA SHEET

Revision date: 10-Feb-2010

Version: 2.0

Page 1 of 7

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

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300  
Contact E-Mail: pfizer-MSDS@pfizer.com

### Material Name: Testosterone Cypionate Injection, USP

Trade Name:	Depo-Testosterone
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used for hormone replacement therapy

## 2. HAZARDS IDENTIFICATION

Appearance: Liquid  
Signal Word: DANGER

Statement of Hazard: May damage fertility or the unborn child.  
Suspected of causing cancer.

Additional Hazard Information:  
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:

Clinical use has caused effects on reproductive system, including prolonged erection (priapism), breast development in males (gynecomastia), loss of libido, decreased sperm count, impairment of male fertility, development of male characteristics (masculinization), development of male characteristics in the female fetus, impairment of female fertility. Clinical use of this drug has caused prostate cancer, liver cancer.

EU Indication of danger:

Toxic to reproduction: Category 1  
Carcinogenic: Category 2

EU Hazard Symbols:



EU Risk Phrases:

R45 - May cause cancer.  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification  
(NOHSC):

# MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP  
Revision date: 10-Feb-2010

Page 2 of 7  
Version: 2.0

## 2. HAZARDS IDENTIFICATION

**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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Xn;R20/22	<1.0
Testosterone Cypionate	58-20-8	200-368-4	Repr.Cat.1;R60-61 Carc.Cat.2;R45	10-20

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
BENZYL BENZOATE	120-51-4	204-402-9	Xn;R22	*
Cottonseed Oil	8001-29-4	232-280-7	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

## 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek 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.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

## 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** Carbon dioxide, carbon monoxide

**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.

## MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP  
Revision date: 10-Feb-2010

Page 3 of 7  
Version: 2.0

### 6. ACCIDENTAL RELEASE MEASURES

<b>Health and Safety Precautions:</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
<b>Measures for Cleaning / Collecting:</b>	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
<b>Measures for Environmental Protections:</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Additional Consideration for Large Spills:</b>	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

<b>General Handling:</b>	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
<b>Storage Conditions:</b>	Store as directed by product packaging. Keep out of reach of children. Protect from light.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

#### Benzyl Alcohol

Bulgaria OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Poland OEL - TWA	Listed

#### Testosterone Cypionate

Pfizer OEL TWA-8 Hr:	4 µg/m <sup>3</sup> , Skin
----------------------	----------------------------

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Environmental Exposure Controls:</b>	Refer to specific Member State legislation for requirements under Community environmental legislation.
<b>Personal Protective Equipment:</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
<b>Hands:</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Respiratory protection:</b>	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

## MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP  
Revision date: 10-Feb-2010

Page 4 of 7  
Version: 2.0

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Clear
Molecular Formula:	Mixture	Molecular Weight:	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 in this section describes the hazards of various forms of the active ingredient.

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

##### **Testosterone Cypionate**

Mouse Intraperitoneal LD 50 > 1000 mg/kg

##### **Testosterone propionate**

Rat Oral LD 50 1000 mg/kg

Mouse Oral LD 50 1350 mg/kg

##### **BENZYL BENZOATE**

Rat Oral LD50 1680 mg/kg

##### **Cottonseed Oil**

Rat Oral LD50 > 90 ml/kg

##### **Benzyl Alcohol**

Rat Oral LD50 1230 mg/kg

Rat Intravenous LD50 53 mg/kg

Rat Inhalation LC50 46 mg/m<sup>3</sup>

**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.

#### Irritation / Sensitization: (Study Type, Species, Severity)

##### **Benzyl Alcohol**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate

Skin Irritation Guinea Pig Moderate

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

##### **Testosterone Cypionate**

5 Day(s) Mouse Oral 200 mg/kg LOAEL Liver

## MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP  
Revision date: 10-Feb-2010

Page 5 of 7  
Version: 2.0

### 11. TOXICOLOGICAL INFORMATION

#### Testosterone propionate

5 Day(s) Mouse Oral 1000 mg/kg/day NOAEL None identified  
28 Day(s) Monkey Subcutaneous 2.7 mg/kg/day LOAEL Endocrine system

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

#### Testosterone propionate

Embryo / Fetal Development Monkey Subcutaneous 1.25 mg/kg/day LOEL Teratogenic  
Embryo / Fetal Development Rat Subcutaneous 0.4 mg/kg NOEL Teratogenic

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

#### Testosterone propionate

Not specified Rat Subcutaneous 80-100 mg LOEL Tumors, Male reproductive system

**Carcinogen Status:** See below

#### Testosterone Cypionate

IARC: Group 2A  
OSHA: Present

#### Testosterone propionate

IARC: Group 2A  
OSHA: Present

### 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. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

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

### 15. REGULATORY INFORMATION

**EU Symbol:** T

# MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP  
Revision date: 10-Feb-2010

Page 6 of 7  
Version: 2.0

## 15. REGULATORY INFORMATION

**EU Indication of danger:** Toxic to reproduction: Category 1  
Carcinogenic: Category 2

**EU Risk Phrases:**  
R45 - May cause cancer.  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.

**EU Safety Phrases:**  
S36/37 - Wear suitable protective clothing and gloves.  
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**  
DANGER  
May damage fertility or the unborn child.  
Suspected of causing cancer.

### Canada - WHMIS: Classifications

**WHMIS hazard class:**  
Class D, Division 2, Subdivision A



### **BENZYL BENZOATE**

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	204-402-9

### **Cottonseed Oil**

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	232-280-7

### **Benzyl Alcohol**

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	202-859-9

### **Testosterone Cypionate**

California Proposition 65	developmental toxicity, initial date 10/1/91 female reproductive toxicity, initial date 4/1/90 male reproductive toxicity, initial date 4/1/90
<b>U.S. Drug Enforcement Administration:</b>	Schedule IIIN Controlled Substance
<b>Australia (AICS):</b>	Listed
<b>Standard for the Uniform Scheduling for Drugs and Poisons:</b>	Schedule 4
<b>EU EINECS/ELINCS List</b>	200-368-4

## MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP  
Revision date: 10-Feb-2010

Page 7 of 7  
Version: 2.0

### 15. REGULATORY INFORMATION

### 16. OTHER INFORMATION

#### Text of R phrases mentioned in Section 3

R45 - May cause cancer.  
R60 - May impair fertility.  
R61 - May cause harm to the unborn child.  
R20/22 - Harmful by inhalation and if swallowed.

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**