



# MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

**Pfizer Inc**  
Pfizer Pharmaceuticals Group  
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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: Estradiol Cypionate Injection, USP**

**Trade Name:** Depo(R)-Estradiol Sterile Solution  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product for the treatment of menopause and/or female hypogonadism

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Chlorobutanol	57-15-8	200-317-6	<1
Estradiol Cypionate	313-06-4	206-237-8	0.5

Ingredient	CAS Number	EU EINECS List	%
Cottonseed Oil	8001-29-4	232-280-7	*

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** Clear pale yellow liquid  
**Signal Word:** DANGER

**Statement of Hazard:** May cause cancer.  
May damage fertility or the unborn child.

**Additional Hazard Information:**  
**Long Term:** Occupational studies have shown that males working with estrogen-like compounds have shown clinical signs of hyperestrogenism including enlarged breasts and milk secretion. Loss of libido, breast tenderness, and changes in sex hormone levels have also occurred. Occupational exposure in females has resulted in menstrual irregularities (breakthrough bleeding, menstrual flow changes, spotting and amenorrhea). Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system the developing fetus. Clinical use of this drug has caused nausea, vomiting, abdominal cramping, weight changes, fluid retention, changes in sexual desire (libido), breast development in males (gynecomastia), loss of hair, mental depression, menstrual irregularities, lack of menstrual periods (amenorrhea), changes in cervical erosion and secretion, breast enlargement, breast pain.

**Known Clinical Effects:**

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

**EU Hazard Symbols:**



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

**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:** Rinse immediately with plenty of water, also under the eyelids, 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. 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:** 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.

### 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.

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### 7. HANDLING AND STORAGE

**General Handling:** Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Estradiol Cypionate

**Pfizer OEL TWA-8 Hr:**

0.2 ug/m<sup>3</sup>, Skin

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

**Analytical Method:** Analytical method available for estradiol. Contact Pfizer Inc for further information.

**Engineering Controls:** Local exhaust ventilation (LEV) should used to control airborne levels.

#### Personal Protective Equipment:

**Hands:** Rubber gloves

**Eyes:** Not required under normal conditions of use. Glasses or goggles are recommended if eye contact is possible.

**Skin:** Not required for the normal use of this product. Wear protective clothing when working with large quantities.

**Respiratory protection:** Not required for the normal use of this product. 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES:

<b>Physical State:</b>	Liquid	<b>Color:</b>	Light yellow - Pale yellow
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Solubility:** Insoluble: Water

### 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)

#### Estradiol Cypionate

Mouse Subcutaneous LD 50 > 1000 mg/kg

**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.

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

#### **Estradiol**

90 Day(s) Rat Oral 0.003 mg/kg/day NOEL Blood, Female reproductive system, Male reproductive system, Endocrine system, Liver

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

#### **Estradiol**

Reproductive & Fertility-Females Rat Oral 0.003 mg/kg/day LOEL Reproductive toxicity  
Embryo / Fetal Development Rat Intramuscular 30 mg/kg/day LOEL Fetotoxicity

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

#### **Estradiol**

Sister Chromatid Exchange Human Lymphocytes Positive  
Micronucleus Human Positive  
Chromosome Aberration Human Negative  
*In Vivo* Direct DNA Damage Hamster Positive  
*In Vivo* Micronucleus Rodent Bone Marrow Negative

#### **Estradiol Cypionate**

Direct DNA Interaction Negative  
*In Vitro* Micronucleus Human Lymphocytes Negative  
*In Vitro* Micronucleus Mouse Lymphoma Negative  
Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative

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

#### **Estradiol**

2 Year(s) Female Mouse Oral 0.1 mg/kg LOEL Tumors, Mammary gland, Female reproductive system

**Carcinogen Status:** See below

#### **Estradiol**

**IARC:** Group 1  
**NTP:** Listed  
**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.

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### 14. TRANSPORT INFORMATION

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

### 15. REGULATORY INFORMATION

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

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

**EU Safety Phrases:**  
S24/25 - Avoid contact with eyes and skin.  
S53 - Avoid exposure - obtain special instructions before use.

**OSHA Label:**  
DANGER  
May cause cancer.  
May damage fertility or the unborn child.

#### Canada - WHMIS: Classifications

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



#### **Chlorobutanol**

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS List	Schedule 3 200-317-6

#### **Estradiol Cypionate**

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	206-237-8

#### **Cottonseed Oil**

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

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EU EINECS List

232-280-7

### 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**