



MATERIAL SAFETY DATA SHEET

Revision date: 06-Apr-2010

Version: 1.2

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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

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

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

Material Name: Estradiol Cypionate Injection, USP

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

2. 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:

EU Classification
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.

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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	EU Classification	%
Chlorobutanol	57-15-8	200-317-6	Xn;R22	<1
Estradiol Cypionate	313-06-4	206-237-8	Not Listed	0.5

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
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: 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.

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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: Avoid contact with eyes, skin and clothing. 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.

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 µg/m³, 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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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

Physical State:	Liquid	Color:	Light yellow - Pale yellow
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solubility:	Insoluble: Water		

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

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10. STABILITY AND REACTIVITY

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

Chlorobutanol

Rat Oral LD50 510 mg/kg

Cottonseed Oil

Rat Oral LD50 > 90 ml/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.

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

Chlorobutanol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

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

Estradiol

90 Day(s) Rat Oral 0.003 mg/kg/day NOAEL 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 LOAEL Reproductive toxicity
Embryo / Fetal Development Rat Intramuscular 30 mg/kg/day LOAEL 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

Chlorobutanol

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11. TOXICOLOGICAL INFORMATION

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Positive
In Vitro Micronucleus Mouse Bone Marrow 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

Waste Treatment Methods: 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
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:
S53 - Avoid exposure - obtain special instructions before use.
S24/25 - Avoid contact with eyes and skin.

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15. REGULATORY INFORMATION

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)

Listed

Australia (AICS):

Listed

Standard for the Uniform Scheduling
for Drugs and Poisons:

Schedule 2

Schedule 3

EU EINECS/ELINCS List

200-317-6

Estradiol Cypionate

Inventory - United States TSCA - Sect. 8(b)

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

206-237-8

Cottonseed Oil

Inventory - United States TSCA - Sect. 8(b)

Listed

Australia (AICS):

Listed

EU EINECS/ELINCS List

232-280-7

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

Data Sources:

Publicly available toxicity information.

Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 3 - Composition / Information on Ingredients.

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