



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

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Material Name: Testosterone Cypionate, Estradiol Cypionate Injection

Trade Name:	DEPO-TESTADIOL®
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used for hormone replacement therapy

2. HAZARDS IDENTIFICATION

Appearance: Clear, oily liquid
Signal Word: WARNING

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

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. 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).

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, menstrual irregularities, breast pain, changes in cervical erosion and secretion, impairment of female fertility. Clinical use of this drug has caused nausea, vomiting, abdominal cramping, fluid retention, weight changes, liver cancer, prostate cancer.

EU Classification
EU Indication of danger:

Toxic to reproduction: Category 1
Carcinogenic: Category 1

EU Hazard Symbols:



EU Risk Phrases:

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2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Testosterone Cypionate	58-20-8	200-368-4	Repr.Cat.1;R60-61 Carc.Cat.2;R45	5
Chlorobutanol	57-15-8	200-317-6	Xn;R22	*
Estradiol Cypionate	313-06-4	206-237-8	Not Listed	<1

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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation or unusual symptoms occur, even if they are delayed.

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 monoxide and carbon dioxide

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.

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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:	Avoid breathing vapor or mist. 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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Testosterone Cypionate
Pfizer OEL TWA-8 Hr:

4 µg/m³, Skin

Estradiol Cypionate
Pfizer OEL TWA-8 Hr:

0.2 µg/m³, Skin

Analytical Method:	Analytical method available for estradiol. Contact Pfizer Inc for further information.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures.
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. Wear safety glasses or goggles 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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Oily liquid	Color:	Clear
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable
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 various forms of the active ingredients.

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

Testosterone propionate

Rat	Oral	LD 50	1000 mg/kg
Mouse	Oral	LD 50	1350 mg/kg

Testosterone Cypionate

Mouse	Para-periosteal	LD 50	> 1000 mg/kg
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Estradiol Cypionate

Mouse	Subcutaneous	LD 50	> 1000 mg/kg
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Cottonseed Oil

Rat	Oral	LD50	> 90 ml/kg
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Chlorobutanol

Rat	Oral	LD50	510 mg/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.

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)

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

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11. TOXICOLOGICAL INFORMATION

Testosterone Cypionate

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

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))

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

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)

Testosterone Cypionate

Bacterial Mutagenicity (Ames)

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

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

Chlorobutanol

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

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

Testosterone propionate

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

Estradiol

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

Carcinogen Status: See below

Testosterone propionate

IARC: Group 2A

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11. TOXICOLOGICAL INFORMATION

OSHA: Present

Testosterone Cypionate

IARC: Group 2A

OSHA: Present

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: Toxic to reproduction: Category 1
Carcinogenic: Category 1

EU Risk Phrases:

R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.

EU Safety Phrases:

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

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15. REGULATORY INFORMATION

OSHA Label:

WARNING

May cause cancer.

May damage fertility or the unborn child

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



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
Schedule IIIN Controlled Substance

U.S. Drug Enforcement Administration:

Australia (AICS):

Standard for the Uniform Scheduling
for Drugs and Poisons:

Listed
Schedule 4

EU EINECS/ELINCS List

200-368-4

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.

R45 - May cause cancer.

R60 - May impair fertility.

R61 - May cause harm to the unborn child.

Data Sources:

Pfizer proprietary drug development information. Publicly available toxicity information.

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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