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

<table>
<thead>
<tr>
<th>Material Name: Testosterone Cypionate, Estradiol Cypionate Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material Name: Testosterone Cypionate, Estradiol Cypionate Injection</td>
</tr>
<tr>
<td>Trade Name: DEPO-TESTADIOL®</td>
</tr>
<tr>
<td>Chemical Family: Mixture</td>
</tr>
<tr>
<td>Intended Use: Pharmaceutical product used for hormone replacement therapy</td>
</tr>
</tbody>
</table>

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: |
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone Cypionate</td>
<td>58-20-8</td>
<td>200-368-4</td>
<td>Repr.Cat.1;R60-61</td>
<td>5</td>
</tr>
<tr>
<td>chlorobutanol</td>
<td>57-15-8</td>
<td>200-317-6</td>
<td>Xn;R22</td>
<td>*</td>
</tr>
<tr>
<td>Estradiol Cypionate</td>
<td>313-06-4</td>
<td>206-237-8</td>
<td>Not Listed</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Cottonseed Oil</td>
<td>8001-29-4</td>
<td>232-280-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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


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.
MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate, Estradiol Cypionate
Injection
Revision date: 06-Apr-2010

9. PHYSICAL AND CHEMICAL PROPERTIES

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

- **Estradiol Cypionate**
  - Mouse  Subcutaneous  LD 50  > 1000 mg/kg

- **Cottonseed Oil**
  - Rat  Oral  LD50  > 90 ml/kg

- **Chlorobutanol**
  - Rat  Oral  LD50  510 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.

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

PZ01147
11. TOXICOLOGICAL INFORMATION

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

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))

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  LOAEL  Reproductive toxicity
Embryo / Fetal Development  Rat  Intramuscular  30 mg/kg/day  LOAEL  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
11. TOXICOLOGICAL INFORMATION

Testosterone Cypionate
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.
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

U.S. Drug Enforcement Administration:
Schedule IIIN Controlled Substance

Australia (AICS):
Listed

Standard for the Uniform Scheduling for Drugs and Poisons:
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.
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