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

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.

Australian Hazard Classification (NOHSC):
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Xn;R20/22</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td>Testosterone Cypionate</td>
<td>58-20-8</td>
<td>200-368-4</td>
<td>Repr.Cat.1;R60-61 Carc.Cat.2;R45</td>
<td>10-20</td>
</tr>
<tr>
<td>BENZYL BENZOATE</td>
<td>120-51-4</td>
<td>204-402-9</td>
<td>Xn;R22</td>
<td>*</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: 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.
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. 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.


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/m³, Skin

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

Engineering Controls: 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.

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: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
<th>Color:</th>
<th>Clear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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 LD50 > 1000 mg/kg

Testosterone propionate
Rat Oral LD50 1000 mg/kg
Mouse Oral LD50 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/m3

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
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
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  
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
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