SAFETY DATA SHEET

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

Product Identifier

Material Name: Testosterone Cypionate Injection, USP
Trade Name: Depo-Testosterone
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used for hormone replacement therapy

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Reproductive Toxicity: Category 1A
Carcinogenicity: Category 1B

EU Classification:
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.

Label Elements

Signal Word: Danger
Hazard Statements:
H360FD - May damage fertility. May damage the unborn child.
H350 - May cause cancer

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP
Revision date: 13-Feb-2015
Version: 4.2

Other Hazards
Australian Hazard Classification (NOHSC):

No data available

Note:
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENZYL BENZOATE</td>
<td>120-51-4</td>
<td>204-402-9</td>
<td>Xn; R22 N; R51-53</td>
<td>Acute Tox. 4 (H302) Aquatic Chronic 2 (H411)</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Xn; R20/22</td>
<td>Acute Tox.4 (H302) Acute Tox.4 (H332)</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>Repr. 1A (H360FD) Carc. 1B (H350)</td>
<td>10-20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cottonseed Oil</td>
<td>8001-29-4</td>
<td>232-280-7</td>
<td>Not Listed</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.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Carbon dioxide, carbon monoxide

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures Personel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe 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.


Specific end use(s): No data available
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Benzyl Alcohol
Bulgaria OEL - TWA 5.0 mg/m³
Czech Republic OEL - TWA 40 mg/m³
Finland OEL - TWA 10 ppm
   45 mg/m³
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³
Poland OEL - TWA 240 mg/m³

Testosterone Cypionate
Pfizer OEL TWA-8 Hr: 4 µg/m³, Skin

Exposure Controls
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.

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

Physical State: Liquid
Odor: No data available.
Molecular Formula: Mixture

Color: Clear
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Testosterone propionate
No data available
Benzyl Alcohol
No data available
BENZYL BENZOATE
No data available
Cottonseed Oil
No data available
Testosterone Cypionate
No data available

Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- Oxidizing Properties: No data available
- 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
- Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information in this section describes the hazards of various forms of the active ingredient.
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.

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

**Testosterone propionate**
- Rat Oral LD50 1000 mg/kg
- Mouse Oral LD50 1350 mg/kg

**Benzyl Alcohol**
- Rat Oral LD50 1230 mg/kg
- Rat Para-periosteal LD50 53mg/kg
- Rat Inhalation LC50 >4.178mg/L

**BENZYL BENZOATE**
- Rat Oral LD50 1680 mg/kg

**Cottonseed Oil**
- Rat Oral LD50 > 90 ml/kg
11. TOXICOLOGICAL INFORMATION

**Testosterone Cypionate**

Mouse  Para-periosteal  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.

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

- Benzyl Alcohol
  - Eye Irritation  Rabbit  Severe
  - Skin Irritation  Rabbit  Minimal
  - Skin Irritation  Guinea Pig  Moderate

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

<table>
<thead>
<tr>
<th>Testosterone propionate</th>
<th>5 Day(s)</th>
<th>Mouse</th>
<th>Oral</th>
<th>1000 mg/kg/day</th>
<th>NOAEL</th>
<th>None identified</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>28 Day(s)</td>
<td>Monkey</td>
<td>Subcutaneous</td>
<td>2.7 mg/kg/day</td>
<td>LOAEL</td>
<td>Endocrine system</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Testosterone Cypionate</th>
<th>5 Day(s)</th>
<th>Mouse</th>
<th>Oral</th>
<th>200 mg/kg</th>
<th>LOAEL</th>
<th>Liver</th>
</tr>
</thead>
</table>

**Reproduction & Development Toxicity:** (Duration, Species, Route, Dose, End Point, Effect(s))

<table>
<thead>
<tr>
<th>Testosterone propionate</th>
<th>Embryo / Fetal Development</th>
<th>Monkey</th>
<th>Subcutaneous</th>
<th>1.25 mg/kg/day</th>
<th>LOEL</th>
<th>Teratogenic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>0.4 mg/kg</td>
<td>NOEL</td>
<td>Teratogenic</td>
<td></td>
</tr>
</tbody>
</table>

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

- Testosterone Cypionate
  - Bacterial Mutagenicity (Ames)

**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 propionate**

- IARC: Group 2A (Probably Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

**Toxicity:** No data available
SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP
Revision date: 13-Feb-2015

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

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

TESTOSTERONE CYPIONATE INJECTION USP
15. REGULATORY INFORMATION

BENZYL BENZOATE
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 204-402-9

Cottonseed Oil
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 232-280-7

Benzyl Alcohol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 202-859-9

Testosterone Cypionate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Developmental toxicity initial date 10/1/91
  Carcinogen (Testosterone and its Esters) 4/1/88
  Male Reproductive Toxicity (Anabolic Steroids) 4/1/90
  Female Reproductive Toxicity (Anabolic Steroids) 4/1/90
- U.S. Drug Enforcement Administration: Schedule II(N) Controlled Substance
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-368-4

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.1A; H360FD - May damage fertility. May damage the unborn child.
Carcinogenicity-Cat.1B; H350 - May cause cancer
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

Xn - Harmful
Toxic to reproduction: Category 1
Carcinogenic: Category 2
N - Dangerous for the environment

R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R22 - Harmful if swallowed.
R20/22 - Harmful by inhalation and if swallowed.
R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 14 - Transport Information.

Revision date: 13-Feb-2015
Prepared by: Product Stewardship Hazard Communication

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