SAFETY DATA SHEET

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

Product Identifier

- Material Name: Testosterone Cypionate Injection (Hospira, Inc.)
- Trade Name: Not established
- 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

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
- Acute Oral Toxicity: Category 4
- Reproductive Toxicity: Category 1A
- Carcinogenicity: Category 1B
- Chronic aquatic toxicity: Category 2

Label Elements

- Signal Word: Danger
- Hazard Statements: H302 - Harmful if swallowed
- H360FD - May damage fertility. May damage the unborn child.
- H350 - May cause cancer
- H411 - Toxic to aquatic life with long lasting effects
Precautionary Statements:
- P202 - Do not handle until all safety precautions have been read and understood
- P264 - Wash hands thoroughly after handling
- P270 - Do not eat, drink or smoke when using this product
- P281 - Use personal protective equipment as required
- P330 - Rinse mouth
- P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
- P308+P313 - IF exposed or concerned: Get medical attention/advice
- P273 - Avoid release to the environment
- P405 - Store locked up
- P391 - Collect spillage
- P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENZYL BENZOATE</td>
<td>120-51-4</td>
<td>204-402-9</td>
<td>Acute Tox. 4 (H302)</td>
<td>20-30</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 2 (H411)</td>
<td></td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Acute Tox.4 (H302)</td>
<td>&lt;1.0</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.4 (H332)</td>
<td></td>
</tr>
<tr>
<td>Testosterone Cypionate</td>
<td>58-20-8</td>
<td>200-368-4</td>
<td>Repr. 1A (H360FD)</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Carc. 1B (H350)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</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></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.
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 firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**
Personnel 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. Cleanup 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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor</td>
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</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
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</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
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<tr>
<td>Partition Coefficient</td>
<td>(Method, pH, Endpoint, Value)</td>
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<tr>
<td>Decomposition Temperature (°C)</td>
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</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
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<tr>
<td>Vapor Pressure (kPa)</td>
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<tr>
<td>Vapor Density (g/ml)</td>
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<tr>
<td>Relative Density</td>
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<tr>
<td>Viscosity</td>
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<tr>
<td>Odor Threshold</td>
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<tr>
<td>Molecular Weight</td>
<td>Mixture</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
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</tr>
<tr>
<td>Flammability (Solids)</td>
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</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
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</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

| Reactivity                      | No data available       |
| Chemical Stability              | Stable under normal conditions of use. |
| Possibility of Hazardous Reactions | No data available |
| 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 | The information in this section describes the hazards of various forms of the active ingredient. |
| General Information:                |                                                     |
11. TOXICOLOGICAL 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. 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.

Known Clinical Effects:

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

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

Benzy1 Alcohol
Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53 mg/kg
Rat Inhalation LC50 >4.178 mg/L

BENZYL BENZOATE
Rat Oral LD50 1680 mg/kg

Cottonseed Oil
Rat Oral LD50 > 90 ml/kg

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)

Benzy1 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)

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

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

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
11. TOXICOLOGICAL INFORMATION

Embryo / Fetal Development: Rat  Subcutaneous  0.4 mg/kg  NOEL  Teratogenic

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:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Benzyl Alcohol
Pimephales promelas (Fathead Minnow)  EPA  LC50  96 Hours  460 mg/L
Daphnia magna (Water Flea)  OECD  EC50  48 Hours  230 mg/L
Pseudokirchneriella subcapitata (Green Alga)  OECD  EC50  72 Hours  500 mg/L

BENZYL BENZOATE
Brachydanio rerio (Zebra fish)  LC50  96 Hours  1.34 mg/L
Algae  EC50  72 Hours  0.475 mg/L
Shrimp  LC50  96 Hours  4.8 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Benzyl Alcohol
Daphnia magna (Water Flea)  OECD  21 Day(s)  EC50  66 mg/L  Reproduction

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
Benzyl Alcohol
OECD  Activated sludge  Ready  92% After  14 Day(s)  Ready

Bio-accumulative Potential: No data available

Mobility in Soil: No data available
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

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

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

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

Testosterone Cypionate
- CERCLA/SARA 313 Emission reporting: Not Listed
15. REGULATORY INFORMATION

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 III N Controlled Substance
Australia (AICS):
Present
EU EINECS/ELINCS List
200-368-4

16. OTHER INFORMATION

Text of CLP/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

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

Reasons for Revision:
Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification.

Revision date: 11-Sep-2018
Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this 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