



MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 1.1

Page 1 of 6

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

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

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Testosterone Cypionate Injection, USP

Trade Name: Depo (R)-Testosterone Sterile Solution
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for hormone replacement therapy

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Testosterone Cypionate	58-20-8	200-368-4	10-20

Ingredient	CAS Number	EU EINECS List	%
BENZYL BENZOATE	120-51-4	204-402-9	*
Cottonseed Oil	8001-29-4	232-280-7	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Liquid
Signal Word: WARNING

Statement of Hazard: Suspected of damaging fertility or the unborn child.
Suspected of causing cancer.

Additional Hazard Information:
Long Term:

Known Clinical Effects: 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.

EU Indication of danger: Toxic to reproduction: Category 1
Carcinogenic: Category 2

EU Hazard Symbols:

MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP
Revision date: 05-Jan-2007

Page 2 of 6
Version: 1.1



EU Risk Phrases:

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.

4. FIRST AID MEASURES

Eye Contact: Rinse immediately with plenty of water, also under the eyelids, 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 occurs.

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 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

MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP
Revision date: 05-Jan-2007

Page 3 of 6
Version: 1.1

General Handling: Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging. Keep out of reach of children.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Testosterone Cypionate

Pfizer OEL TWA-8 Hr: 4 ug/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.

Personal Protective Equipment:

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.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Liquid

Color: Clear

Molecular Formula: Mixture

Molecular Weight: Mixture

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 LD 50 > 1000 mg/kg

Testosterone propionate

Rat Oral LD 50 1000 mg/kg

Mouse Oral LD 50 1350 mg/kg

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

Testosterone Cypionate

MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP
Revision date: 05-Jan-2007

Page 4 of 6
Version: 1.1

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

Testosterone propionate

5 Day(s) Mouse Oral 1000 mg/kg/day NOEL None identified
28 Day(s) Monkey Subcutaneous 2.7 mg/kg/day LOEL 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.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T

MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP
Revision date: 05-Jan-2007

Page 5 of 6
Version: 1.1

EU Indication of danger: Toxic to reproduction: Category 1
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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:
WARNING
Suspected of damaging 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)	Present
Australia (AICS):	Present
EU EINECS List	204-402-9

Cottonseed Oil

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-280-7

Testosterone Cypionate

California Proposition 65	developmental toxicity, initial date 10/1/91
Drug Enforcement Administration:	Schedule III
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	200-368-4

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

MATERIAL SAFETY DATA SHEET

Material Name: Testosterone Cypionate Injection, USP
Revision date: 05-Jan-2007

Page 6 of 6
Version: 1.1

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End of Safety Data Sheet