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

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Monday - Friday, 8:30am to 5:30pm, Eastern

Standard Time.

Material Name: Animal Test Testosterone Booster

, USP

Trade Name: Testosterone **Chemical Family:** Mixture

Intended Use: Pharmaceutical product used for hormone replacement therapy and as anabolic steroid

Appearance: Capsule Signal Word: DANGER

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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:

2. HAZARDS IDENTIFICATION

EU Risk Phrases:

R45 - May cause cancer. R60 - May impair fertility.

R61 - May cause harm to the unborn child. Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in

accordance with standards for workplace safety, which

regardless of

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Benzyl Alcohol	100-51-6	202-859-9	Xn;R20/22	<1.0
Testosterone Cypionate	58-20-8	200-368-4	Repr.Cat.1;R60-61 Carc.Cat.2;R45	10-20
Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
BENZYL BENZOATE	120-51-4	204-402-9	Xn;R22	*
Cottonseed Oil	8001-29-4	232-280-7	Not Listed	*

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

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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 selfcontained

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

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. Keep out of reach of children. Protect from light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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Benzyl Alcohol

Bulgaria OEL - TWA

Czech Republic OEL - TWA

Listed

Latvia 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

Physical State:CapsuleColor:ClearMolecular Formula:MixtureMolecular 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

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Testosterone propionate

Rat Oral LD 50 1000 mg/kg Mouse Oral LD 50 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

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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

<u>Carcinogen Status:</u> 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:

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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:

 $\ensuremath{\mathsf{S36/37}}$ - 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



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BENZYL BENZOATE Listed

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Listed
204-402-9

EU EINECS/ELINCS List

Cottonseed Oil Listed

Inventory - United States TSCA - Sect. 8(b) Listed
Australia (AICS): 232-280-7

EU EINECS/ELINCS List

Benzyl Alcohol Listed

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Listed
202-859-9

EU EINECS/ELINCS List

Testosterone Cypionate developmental toxicity, initial date 10/1/91

California Proposition 65 female reproductive toxicity, initial date

4/1/90 male reproductive toxicity, initial date

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4/1/90

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

Australia (AICS): Listed
Standard for the Uniform Scheduling Schedule 4

for Drugs and Poisons: 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

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End of Safety Data Sheet