

### SECTION 1: Identification

#### 1.1. Identification

Product form : Mixture  
Trade name : Testopel (testosterone pellets)

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Testopel is FDA approved for testosterone replacement therapy in adult males for conditions associated with low or absent testosterone in the body

#### 1.3. Details of the supplier of the safety data sheet

Endo Pharmaceuticals, Inc.  
1400 Atwater Drive  
Malvern, PA 19355  
(484) 216-0000  
[www.endo.com](http://www.endo.com)

#### 1.4. Emergency telephone number

Emergency number : 1-800-535-5053 24 hours

### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

##### GHS-US classification

Carc. 1B H350 - May cause cancer  
Repr. 2 H361 - Suspected of damaging fertility or the unborn child

Full text of H-statements: see section 16

#### 2.2. Label elements

##### GHS-US labelling

Hazard pictograms (GHS-US) :



GHS08

Signal word (GHS-US) : Danger  
Hazard statements (GHS-US) : H350 - May cause cancer  
H361 - Suspected of damaging fertility or the unborn child  
Precautionary statements (GHS-US) : P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P280 - Wear protective gloves, eye protection, protective clothing  
P308+P313 - If exposed or concerned: Get medical advice/attention  
P405 - Store locked up  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

#### 2.3. Other hazards

other hazards which do not result in classification : Clinical use has caused effects on reproductive system, including prolonged erection (priapism), breast development in males (gynecomastia), decreased sperm count, impairment of male fertility, development of male characteristics (masculinization), development of male characteristics in the female fetus, impairment of female fertility. This drug is Pregnancy Category X. There are rare reports of hepatocellular carcinoma in patients receiving long-term therapy with androgens in high doses. Withdrawal of the drugs did not lead to regression of the tumors in all cases.

#### 2.4. Unknown acute toxicity (GHS US)

Not applicable

### SECTION 3: Composition/information on ingredients

#### 3.1. Substance

Not applicable

# Testopel (testosterone pellets)

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according to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

### 3.2. Mixture

Name	Product identifier	%	GHS-US classification
Testosterone	(CAS No) 58-22-0	96.2	Carc. 1B, H350 Repr. 2, H361

Full text of H-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
- First-aid measures after inhalation : If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
- First-aid measures after skin contact : Wash with plenty of soap and water. Wash contaminated clothing before reuse. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. In all cases of doubt, or when symptoms persist, seek medical advice.
- First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention.
- First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

### 4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/injuries after inhalation : Under normal condition of use; inhalation of fine dust particles is not expected to occur. Dust of the product, if present, may cause respiratory irritation after an excessive inhalation exposure.
- Symptoms/injuries after skin contact : If user operations generate dust or fumes, dust may cause mechanical irritation.
- Symptoms/injuries after eye contact : If user operations generate dust or fumes, dust may cause mechanical irritation.
- Symptoms/injuries after ingestion : Ingestion may cause nausea and vomiting.

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- Suitable extinguishing media : Use fire-extinguishing media appropriate for surrounding materials. Foam. Dry powder. Carbon dioxide. Water spray. Sand.
- Unsuitable extinguishing media : None known.

### 5.2. Special hazards arising from the substance or mixture

- Fire hazard : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases.
- Explosion hazard : No direct explosion hazard.
- Reactivity : The product is non-reactive under normal conditions of use, storage and transport.

### 5.3. Advice for firefighters

- Firefighting instructions : Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protective equipment for firefighters : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid breathing dust, mist or spray. Avoid raising powdered materials into airborne dust.

#### 6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. Minimize generation of dust. Store away from other materials. Discard as medical waste. Clean up operations should only be undertaken by trained personnel.

### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13: Disposal considerations.

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### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Local ventilation at the workplace is recommended. Avoid breathing dust.
- Hygiene measures : Wash exposed skin thoroughly with soap and water after handling. Take care for general good hygiene and housekeeping.

#### 7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.
- Storage conditions : Keep only in the original container in a cool well ventilated place. Keep container closed when not in use. Store at refrigerated temperatures for product stability. Call manufacturer if stored otherwise.
- Incompatible materials : Strong oxidizers.
- Storage temperature : 2 - 8 °C (35.6 - 46.4 °F )

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

No additional information available

#### 8.2. Exposure controls

- Appropriate engineering controls : A washing facility/water for eye and skin cleaning purposes should be present. Avoid raising powdered materials into airborne dust. Provide adequate ventilation to minimize dust concentrations.
- Hand protection : Wear protective gloves.
- Eye protection : Chemical goggles or safety glasses.
- Skin and body protection : Wear suitable protective clothing.
- Respiratory protection : No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation. Where excessive vapor, mist, or dust may result, use approved respiratory protection equipment.
- Other information : Do not eat, drink or smoke during use.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

- Physical state : Solid
- Appearance : Pellets.
- Color : White
- Odor : Odorless
- Odor threshold : No data available
- pH : No data available
- Melting point : 155 °C
- Freezing point : No data available
- Boiling point : No data available
- Flash point : No data available
- Relative evaporation rate (butyl acetate=1) : No data available
- Flammability (solid, gas) : No data available
- Explosive limits : No data available
- Explosive properties : No data available
- Oxidizing properties : No data available
- Vapor pressure : No data available
- Relative density : No data available
- Relative vapor density at 20 °C : No data available
- Solubility : Soluble in chloroform.  
Water: Insoluble  
Ethanol: Slightly soluble  
Ether: Slightly soluble
- Log Pow : No data available

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Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under recommended storage conditions.

### 10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

### 10.4. Conditions to avoid

Do not store at temperatures lower than 2°C or higher than 8°C (for product stability).

### 10.5. Incompatible materials

Strong oxidizers.

### 10.6. Hazardous decomposition products

Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Likely routes of exposure	: Ingestion; Inhalation; Skin and eye contact
Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: May cause cancer.

#### Testosterone (58-22-0)

IARC group	2A - Probably carcinogenic to humans
In OSHA Hazard Communication Carcinogen list	Yes

Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: Under normal condition of use; inhalation of fine dust particles is not expected to occur. Dust of the product, if present, may cause respiratory irritation after an excessive inhalation exposure.
Symptoms/injuries after skin contact	: If user operations generate dust or fumes, dust may cause mechanical irritation.
Symptoms/injuries after eye contact	: If user operations generate dust or fumes, dust may cause mechanical irritation.
Symptoms/injuries after ingestion	: Ingestion may cause nausea and vomiting.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : Mixture not tested.

### 12.2. Persistence and degradability

#### Testopel (testosterone pellets)

Persistence and degradability	Not established.
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### 12.3. Bioaccumulative potential

#### Testopel (testosterone pellets)

Bioaccumulative potential	Not established.
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### 12.4. Mobility in soil

No additional information available

### 12.5. Other adverse effects

Effect on the global warming : No additional information available  
Other information : Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Discard as medical waste.  
Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

### Department of Transportation (DOT)

In accordance with DOT  
Not regulated for transport

### TDG

No additional information available

### Transport by sea

No additional information available

### Air transport

No additional information available

## SECTION 15: Regulatory information

### 15.1. US Federal regulations

All components of this product are listed, or excluded from listing, on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory

This product or mixture does not contain a toxic chemical or chemicals in excess of the applicable concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

### 15.2. International regulations

#### CANADA

##### Testosterone (58-22-0)

Listed on the Canadian DSL (Domestic Substances List)

#### EU-Regulations

No additional information available

#### National regulations

##### Testosterone (58-22-0)

Listed on the AICS (Australian Inventory of Chemical Substances)  
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)  
Listed on the Japanese ISHL (Industrial Safety and Health Law)  
Listed on the Korean ECL (Existing Chemicals List)  
Listed on NZIoC (New Zealand Inventory of Chemicals)  
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)

### 15.3. US State regulations

California Proposition 65 - This product contains, or may contain, trace quantities of a substance(s) known to the state of California to cause cancer, developmental and/or reproductive harm

##### Testosterone (58-22-0)

U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	Non-significant risk level (NSRL)
Yes	No	No	No	

## SECTION 16: Other information

Sources of Key data : Data arise from reference works and literature.  
Date of Revision : 09/24/2015

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Other information : None.

Full text of H-statements:

Carc. 1B	Carcinogenicity, Category 1B
Repr. 2	Reproductive toxicity, Category 2
H350	May cause cancer
H361	Suspected of damaging fertility or the unborn child

SDS US (GHS HazCom 2012)

*The information contained herein is furnished without warranty of any kind. The above information is believed to be correct but does not purport to be all-inclusive and should be used only as a guide. Users should make independent determinations of the suitability and completeness of information from all sources to assure proper use and disposal of these materials and the safety and health of employees and customers.*