

# Testim® 1% (testosterone gel)

## Safety Data Sheet 006

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

Date of issue: 06/27/2016

Version: 1.1

### SECTION 1: Identification

#### 1.1. Identification

Product form : Mixture  
Trade name : Testim® 1% (testosterone gel)

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

Use of the substance/mixture : Pharmaceutical product packaged in 5 g tubes for patient use

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

##### Manufacture:

Endo Pharmaceuticals, Inc.  
1400 Atwater Dr.  
Malvern, PA 19355  
(484) 216-0000

#### 1.4. Emergency telephone number

Emergency number : 1-800-535-5053

### SECTION 2: Hazard(s) identification

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

##### GHS-US classification

Flam. Liq. 2 Highly flammable liquid and vapor  
Eye Irrit. 2A Causes serious eye irritation  
Skin Sens. 1 May cause an allergic skin reaction  
Carc. 1B May cause cancer  
Repr. 2 Suspected of damaging fertility or the unborn child

#### 2.2. Label elements

##### GHS-US labelling

Hazard pictograms (GHS-US) :



GHS02

GHS07

GHS08

Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

Highly flammable liquid and vapor  
May cause an allergic skin reaction  
Causes serious eye irritation  
May cause cancer  
Suspected of damaging fertility or the unborn child

Precautionary statements (GHS-US) :

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Keep away from heat, hot surfaces, open flames, sparks. - No smoking  
Keep container tightly closed  
Ground/bond container and receiving equipment  
Use explosion-proof ventilating, lighting, electrical equipment  
Use only non-sparking tools  
Take precautionary measures against static discharge  
Avoid breathing vapors, mist  
Wash hands thoroughly after handling  
Contaminated work clothing must not be allowed out of the workplace  
Wear protective gloves, eye protection, protective clothing  
If on skin: Wash with plenty of water  
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower  
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
If exposed or concerned: Get medical advice/attention  
If skin irritation or rash occurs: Get medical advice/attention  
If eye irritation persists: get medical advice/attention  
Wash contaminated clothing before reuse  
In case of fire: Use carbon dioxide (CO<sub>2</sub>), dry extinguishing powder, extinguishing powder to

# Testim® 1% (testosterone gel)

## Safety Data Sheet

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

extinguish  
Store in a well-ventilated place. Keep cool  
Store locked up  
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

No additional information available

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

Not applicable

## SECTION 3: Composition/information on ingredients

### 3.1. Substance

Not applicable

### 3.2. Mixture

Name	Product identifier	%	GHS-US classification
Ethanol	(CAS No) 64-17-5	73.6	Flam. Liq. 2 Eye Irrit. 2A Asp. Tox. 1
Oxacyclohexadecan-2-one	(CAS No) 106-02-5	8	Skin Sens. 1B
Testosterone	(CAS No) 58-22-0	1	Carc. 1B Repr. 2

## 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 : Remove person to fresh air and keep 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. If vomiting occurs naturally, have victim lean forward to reduce risk of aspiration. Call a poison center or a doctor if you feel unwell.

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

Symptoms/injuries after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

Symptoms/injuries after skin contact : May cause an allergic skin reaction. This product contains small amounts of an ingredient which has been reported to cause skin sensitization reactions in humans and guinea pigs.

Symptoms/injuries after eye contact : Eye irritation. May cause moderate irritation, including burning sensation, tearing, redness or swelling.

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 : Highly flammable. 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.

# Testim® 1% (testosterone gel)

## Safety Data Sheet

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

Protective equipment for firefighters : Do not enter fire area without proper protective equipment, including respiratory protection. Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

### SECTION 6: Accidental release measures

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

##### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Evacuate unnecessary personnel. Avoid contact with skin and eyes.

##### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".

#### 6.2. Environmental precautions

Avoid release to the environment.

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

Methods for cleaning up : Take up liquid spill into absorbent material. Sweep up dry powder and dispose properly. Store away from other materials. Discard as medical waste. Clean up operations should only be undertaken by trained personnel.

Other information : Dispose of materials or solid residues at an authorized site.

#### 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.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. 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 contact with skin and eyes. Wear personal protective equipment.

Hygiene measures : Wash exposed skin thoroughly with soap and water after handling. Take care for general good hygiene and housekeeping. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

#### 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 locked up.

Incompatible materials : None known.

Storage temperature : < 86 °F

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Ethanol (64-17-5)		
ACGIH	ACGIH STEL (ppm)	1000 ppm
ACGIH	Remark (ACGIH)	URT irr
OSHA	OSHA PEL (TWA) (mg/m <sup>3</sup> )	1900 mg/m <sup>3</sup>
OSHA	OSHA PEL (TWA) (ppm)	1000 ppm

#### 8.2. Exposure controls

Appropriate engineering controls : A washing facility/water for eye and skin cleaning purposes should be present. Ensure good ventilation of the work station.

Hand protection : Wear protective gloves.

Eye protection : Chemical goggles or safety glasses. 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.

Environmental exposure controls : Avoid release to the environment.

Other information : Do not eat, drink or smoke during use.

# Testim® 1% (testosterone gel)

## Safety Data Sheet

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

### SECTION 9: Physical and chemical properties

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

Physical state	: Liquid
Appearance	: Gel.
Color	: Clear
Odor	: Alcohol odor
Odor threshold	: No data available
pH	: 5 - 6.5
Melting point	: Not applicable
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	: Water: Miscible
Log Pow	: No data available
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

Excessive heat.

#### 10.5. Incompatible materials

None known.

#### 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

Ethanol (64-17-5)	
LD50 oral rat	7060 mg/kg
LC50 inhalation rat (mg/l)	124.7 mg/l/4h
Oxacyclohexadecan-2-one (106-02-5)	
LD50 oral rat	> 5 g/kg

# Testim® 1% (testosterone gel)

## Safety Data Sheet

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

Skin corrosion/irritation	: Not classified pH: 5 - 6.5
Serious eye damage/irritation	: Causes serious eye irritation. pH: 5 - 6.5
Respiratory or skin sensitization	: May cause an allergic skin reaction.
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	: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
Symptoms/injuries after skin contact	: May cause an allergic skin reaction. This product contains small amounts of an ingredient which has been reported to cause skin sensitization reactions in humans and guinea pigs.
Symptoms/injuries after eye contact	: Eye irritation. May cause moderate irritation, including burning sensation, tearing, redness or swelling.
Symptoms/injuries after ingestion	: Ingestion may cause nausea and vomiting.

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : Mixture not tested.

Ethanol (64-17-5)	
LC50 fish 1	12.0 - 16.0 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
LC50 other aquatic organisms 1	5012 mg/l 48 hours- daphnia
EC50 Daphnia 1	9268 - 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 fish 2	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 2	2 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
ErC50 (algae)	275 mg/l
ErC50 (other aquatic plants)	4432 mg/l
NOEC (acute)	9.6 mg/l Daphnia magna

### 12.2. Persistence and degradability

Testim® 1% (testosterone gel)	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

Testim® 1% (testosterone gel)	
Bioaccumulative potential	Not established.

Ethanol (64-17-5)	
Log Pow	-0.32

### 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 treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Discard as medical waste.

# Testim® 1% (testosterone gel)

## Safety Data Sheet

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

Ecology - waste materials : Avoid release to the environment.

### SECTION 14: Transport information

#### Department of Transportation (DOT)

In accordance with DOT

Transport document description : UN1170 Ethanol solutions, 3, II  
UN-No.(DOT) : UN1170  
Proper Shipping Name (DOT) : Ethanol solutions  
Class (DOT) : 3 - Class 3 - Flammable and combustible liquid 49 CFR 173.120  
Packing group (DOT) : II - Medium Danger  
Hazard labels (DOT) : 3 - Flammable liquid



DOT Packaging Non Bulk (49 CFR 173.xxx) : 202  
DOT Packaging Bulk (49 CFR 173.xxx) : 242  
DOT Special Provisions (49 CFR 172.102) : 24 - Alcoholic beverages containing more than 70 percent alcohol by volume must be transported as materials in Packing Group II. Alcoholic beverages containing more than 24 percent but not more than 70 percent alcohol by volume must be transported as materials in Packing Group III  
IB2 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized  
T4 - 2.65 178.274(d)(2) Normal..... 178.275(d)(3)  
TP1 - The maximum degree of filling must not exceed the degree of filling determined by the following: Degree of filling =  $97 / (1 + a (tr - tf))$  Where: tr is the maximum mean bulk temperature during transport, and tf is the temperature in degrees celsius of the liquid during filling  
DOT Packaging Exceptions (49 CFR 173.xxx) : 4b;150  
DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 5 L  
DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : 60 L  
DOT Vessel Stowage Location : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel  
Emergency Response Guide (ERG) Number : 127  
Other information : No supplementary information available.

#### TDG

Transport document description : UN1170 ETHANOL SOLUTION (more than 24 per cent ethanol, by volume), 3, II  
UN-No. (TDG) : UN1170  
Proper Shipping Name (TDG) : ETHANOL SOLUTION  
TDG Primary Hazard Classes : 3 - Class 3 - Flammable Liquids  
Packing group : II - Medium Danger  
TDG Special Provisions : 150 - An emergency response assistance plan (ERAP) is required for these dangerous goods under subsection 7.1(6) of Part 7 (Emergency Response Assistance Plan)  
Explosive Limit and Limited Quantity Index : 1 L  
Passenger Carrying Road Vehicle or Passenger Carrying Railway Vehicle Index : 5 L

#### Transport by sea

UN-No. (IMDG) : 1170  
Proper Shipping Name (IMDG) : ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)  
Class (IMDG) : 3 - Flammable liquids  
Packing group (IMDG) : II - substances presenting medium danger  
Limited quantities (IMDG) : 1 L

# Testim® 1% (testosterone gel)

## Safety Data Sheet

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

### Air transport

UN-No. (IATA)	: 1170
Proper Shipping Name (IATA)	: Ethanol solution
Class (IATA)	: 3 - Flammable Liquids
Packing group (IATA)	: II - Medium Danger

## 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)

##### Ethanol (64-17-5)

Listed on the Canadian DSL (Domestic Substances List)

WHMIS Classification

Class B Division 2 - Flammable Liquid  
Class D Division 2 Subdivision B - Toxic material causing other toxic effects

##### Oxacyclohexadecan-2-one (106-02-5)

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)

##### Ethanol (64-17-5)

Listed on IARC (International Agency for Research on Cancer)  
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 ENCS (Existing & New Chemical Substances) inventory  
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)  
Listed on the Canadian IDL (Ingredient Disclosure List)  
Listed on INSQ (Mexican national Inventory of Chemical Substances)  
Listed on CICR (Turkish Inventory and Control of Chemicals)

##### Oxacyclohexadecan-2-one (106-02-5)

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 ENCS (Existing & New Chemical Substances) inventory  
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)  
Listed on INSQ (Mexican national Inventory of Chemical Substances)  
Listed on CICR (Turkish Inventory and Control of Chemicals)

### 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

# Testim® 1% (testosterone gel)

## Safety Data Sheet

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

<b>Testosterone (58-22-0)</b>				
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	
<b>Ethanol (64-17-5)</b>				
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	Yes	No	No	

### SECTION 16: Other information

Sources of Key data : Data arise from reference works and literature.  
Date of Revision : 09/24/2015  
Other information : None.

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.*