

## Safety Data Sheet

### Testosterone gel, 1.62%

#### SECTION 1 IDENTIFICATION

<b>Product identifier</b>	Testosterone gel, 1.62%
<b>Recommended use</b>	Topical
<b>Manufacturer</b>	
<b>Company name</b>	TWi Pharmaceuticals, Inc.
<b>Address</b>	3F, No 41, Lane 221, Kang Chien Rd, Taipei, Taiwan.
<b>Telephone</b>	886-2-26573350
<b>Fax</b>	886-2-26573391
<b>E-mail address</b>	QA.Service@twipharma.com
<b>Emergency phone number</b>	1-844-518-2989

#### SECTION 2 HAZARD IDENTIFICATION

<b>Hazard statement</b>	H226 - Flammable liquid and vapor H351 - Suspected of causing cancer H360 - May damage fertility or the unborn child
<b>Precautionary statement</b>	P202 - Do not handle until all safety precautions have been read and understood P308 + P313 - IF exposed or concerned: Get medical advice/attention P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking P233 - Keep container tightly closed P280 - Wear protective gloves/protective clothing/eye protection/face protection P403 + P235 - Store in a well-ventilated place. Keep cool

#### SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	Weight (%)	EU - GHS Substance Classification	CAS#
Ethanol	55-70	Flam. Liq. 2 (H226)	64-17-5
Water	20-30	Not Hazardous*	7732-18-5
Testosterone	1-2	Carc. 2 (H351) Repr. 1B (H360)	58-22-0

Not Hazardous\* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

#### SECTION 4 FIRST-AID MEASURES

**First aid measures**  
**Inhalation**

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

<b>Skin contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Eye contact</b>	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Ingestion</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary
<b>Protection of First-aiders</b>	Use personal protective equipment
<b>Most important symptoms and effects</b>	None known from occupational exposure
<b>Medical Conditions Aggravated by Exposure</b>	None known from occupational exposure
<b>Notes To Physician</b>	Treat symptomatically

## SECTION 5 FIRE-FIGHTING MEASURES

<b>Extinguishing Media</b>	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide
<b>Special hazards arising from the substance or mixture</b>	Keep away from heat, sparks and flame.
<b>Advice for firefighters</b>	As in any fire, wear self-contained breathing apparatus and full protective gear.

## SECTION 6 ACCIDENTAL RELEASE MEASURES

<b>Personal precautions and Protective Equipment</b>	For personal protection see section 8.
<b>Emergency Precautions</b>	Should not be released into the environment.
<b>Methods for Containment and Clean-up</b>	Keep away from ignition sources. Ventilate area. Take up mechanically and collect in suitable container for disposal.
<b>Incompatibilities</b>	Strong acids and bases.

## SECTION 7 HANDLING AND STORAGE

<b>Handling</b>	Handle in accordance with good industrial hygiene and safety practice.
<b>Storage</b>	Store according to label instructions.

## SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>Engineering Controls</b>	No special provisions are required under normal product use conditions
<b>Respiratory Protection</b>	Respiratory protection is not needed during normal product use.
<b>Individual Protection Measures</b>	
<b>Eye</b>	Eye protection not required during typical product use conditions
<b>Gloves</b>	Gloves not required during normal product use conditions.
<b>Other PPE Data</b>	Wear appropriate body coverings if contact may occur. Suitable work clothes. Wash hands before breaks and at the end of the work shift.
<b>Environmental Exposure Controls</b>	Not determined

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

### Appearance

<b>Physical state/ Form</b>	Clear colorless gel
<b>Odor</b>	Alcohol odor.
<b>Odor threshold</b>	Not determined
<b>pH</b>	Not determined
<b>Melting point/ Freezing point</b>	Not determined
<b>Flash Point Method</b>	Tag Closed Cup (TCC)
<b>Flash point</b>	25
<b>Evaporation rate at 20°C</b>	Not determined
<b>Flammability (Solid)</b>	Not determined
<b>Upper/lower flammability</b>	Not determined.
<b>Vapor pressure/Vapor density</b>	Not determined
<b>Solubility</b>	Not determined
<b>Partition coefficient</b>	Not determined
<b>Auto-ignition temperature</b>	Not determined
<b>Decomposition temperature</b>	Not determined
<b>Viscosity (centipoise)</b>	9000-29000 Liquid Flow time > 100 seconds
<b>Explosion Severity</b>	Not determined
<b>Oxidizer Properties</b>	Not determined
<b>Initial boiling point and boiling range</b>	> 78°C

## SECTION 10 STABILITY AND REACTIVITY

Stable under recommended storage conditions. Avoid contact with heat, sparks, open flame, and static discharge.

## SECTION 11 TOXICOLOGICAL INFORMATION

**Exposure Route** Dermal

### Acute Toxicity - Oral

Chemical Name	Acute Test	Value	Units	Species
Ethanol 64-17-5	LD50 =	3450 6300 7060 5560	mg/kg	Mice Liquid Rabbits Liquid Rats Liquid Guinea Pigs
Testosterone 58-22-0	LD50 >	5000	mg/kg	Mammals

<b>Acute Toxicity – Dermal</b>	Not determined
<b>Acute Toxicity – Inhalation</b>	Not determined
<b>Corrosivity</b>	Not determined
<b>Dermal Irritation</b>	Not determined
<b>Eye irritation</b>	Not determined

<b>Sensitization</b>	Not determined
<b>Toxicokinetics/Metabolism</b>	Not determined
<b>Target Organ Effects</b>	Not determined
<b>Reproductive Effects</b>	In humans adverse reproductive effects include: fetal abnormalities. testicular atrophy. Pregnancy Category X : Contraindicated in Pregnancy
<b>Carcinogenicity</b>	In humans, produced tumors of the liver In animals, produced tumors of the male reproductive system, mammary gland, ovaries, uterus IARC Group 2A (probably carcinogenic to humans).
<b>Mutagenicity</b>	Not determined
<b>Aspiration hazard</b>	Not determined

## SECTION 12 ECOLOGICAL INFORMATION

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

## SECTION 13 DISPOSAL CONSIDERATIONS

Disposal should be made in accordance with country, federal, state and local regulations.

## SECTION 14 TRANSPORT INFORMATION

### ICAO/IATA

<b>Status</b>	Regulated
<b>14.1. UN number</b>	UN1170
<b>14.2. Proper shipping name</b>	Ethanol solution
<b>14.3. Hazard class</b>	3
<b>14.4. Packing group</b>	III
<b>14.5. Environmental hazard</b>	Not applicable
<b>14.6. Special provisions</b>	IATA 3.3.3, ICAO 3.2.3
<b>14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:</b>	Not applicable

### US DOT

<b>Status:</b>	Regulated
<b>14.1. UN number</b>	UN1170
<b>14.2. Proper shipping name</b>	Ethanol solution, Limited Quantity
<b>14.3. Hazard class</b>	3

### ADR

<b>Status:</b>	Not regulated
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### IMDG/IMO

<b>Status:</b>	Regulated
<b>14.1. UN number</b>	UN1170
<b>14.2. Proper shipping name</b>	Ethanol solution
<b>14.3. Hazard class</b>	3
<b>14.4. Packing group</b>	III
<b>14.5. Special provisions:</b>	IMDG 2.3.2.2

## SECTION 15 REGULATORY INFORMATION

Generic Medicine

## SECTION 16 OTHER INFORMATION

No information found.

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<b>Version #</b>	04
<b>Disclaimer</b>	TWi Pharmaceutical, Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.