

Testosterone Gel 4.5%

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Testosterone Gel 4.5%

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

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

Trimel Pharmaceuticals
2488 Dunwin Drive
Mississauga, Ontario L5L 1J9 - Canada
T 905-817-8184

1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Carc. 1B H350
Repr. 1A H360
Lact H362

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
H360 - May damage fertility or the unborn child
H362 - May cause harm to breast-fed children

Precautionary statements (GHS-US) : P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapours/spray
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash ... thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308+P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

Full text of H-phrases: see section 16

3.2. Mixture

Name	Product identifier	%	GHS-US classification
Castor oil	(CAS No) 8001-79-4	Proprietary	Not classified
Testosterone	(CAS No) 58-22-0	4.5	Acute Tox. 4 (Oral), H302 Carc. 1B, H350 Lact, H362 Repr. 1A, H360 Aquatic Acute 1, H400

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SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: No specific first aid necessary for this route of exposure.
First-aid measures after skin contact	: No specific first aid necessary for this route of exposure.
First-aid measures after eye contact	: Flush with plenty of water for at least 15 minutes. Seek medical advice if irritation develops or persists.
First-aid measures after ingestion	: If the material is swallowed, get immediate medical attention or advice. DO NOT induce vomiting unless directed to do so by medical personnel.

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

Symptoms/injuries after inhalation	: None under normal use.
Symptoms/injuries after skin contact	: None under normal use.
Symptoms/injuries after eye contact	: May cause slight irritation.
Symptoms/injuries after ingestion	: Harmful if swallowed.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
Explosion hazard	: None known.

5.3. Advice for firefighters

Protection during firefighting	: Firefighters should wear full protective gear.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
Methods for cleaning up	: Confine spill and soak up with absorbent. Place in an approved container and dispose in accordance with local, state and federal regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: No special handling required.
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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: No special storage conditions required.
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7.3. Specific end use(s)

Pharmaceutical

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls	: None required under normal product handling conditions.
Hand protection	: None required under normal product handling conditions.
Eye protection	: None required under normal product handling conditions.
Skin and body protection	: None required under normal product handling conditions.

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Respiratory protection : None required under normal product handling conditions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Gel
Color	: Clear
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Viscosity	: 10,000 mPa.s
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

None.

10.5. Incompatible materials

Not determined.

10.6. Hazardous decomposition products

Not determined.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: May cause cancer.

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IARC group

2A

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Reproductive toxicity	: May damage fertility or the unborn child. May cause harm to breast-fed children.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

In accordance with DOT

14.1. UN number

Not a dangerous good in sense of transport regulations

14.2. UN proper shipping name

Not applicable

SECTION 15: Regulatory information

15.1. US Federal regulations

Castor oil (8001-79-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Testosterone (58-22-0)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

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	No significance risk level (NSRL)
Yes				

Testosterone (58-22-0)

U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — AcuteHazard, Category 1
Carc. 1B	Carcinogenicity, Category 1B
Lact	Reproductive toxicity, Additional category, Effects on or via lactation
Repr. 1A	Reproductive toxicity, Category 1A

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H302	Harmful if swallowed
H350	May cause cancer
H360	May damage fertility or the unborn child
H362	May cause harm to breast-fed children
H400	Very toxic to aquatic life

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product