

Testosterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.11.2019
1.1	10.10.2020	5330128-00002	Date of first issue: 26.11.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Testosterone Formulation

Manufacturer or supplier's details

Company name of supplier	: MSD
Address	: Avenida 16 de Septiembre No. 301 Xaltocan - Xochimilco Mexico 16090
Telephone	: 52 55 57284444
Telefax	: 908-735-1496
Emergency telephone	: 1-908-423-6000
E-mail address	: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin irritation	: Category 3
Carcinogenicity	: Category 1B
Reproductive toxicity	: Category 1B
Specific target organ toxicity - repeated exposure	: Category 1 (Testis)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements	: H316 Causes mild skin irritation. H350 May cause cancer. H360 May damage fertility or the unborn child. H372 Causes damage to organs (Testis) through prolonged or repeated exposure.
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Precautionary Statements	: Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
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Response:

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P308 + P313 IF exposed or concerned: Get medical advice/attention.
P332 + P313 If skin irritation occurs: Get medical advice/attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Testosterone	58-22-0	>= 10 -< 20

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Causes mild skin irritation.
May cause cancer.
May damage fertility or the unborn child.
Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment. |
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SECTION 6. ACCIDENTAL RELEASE MEASURES

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|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up | : | Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

SECTION 7. HANDLING AND STORAGE

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| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |

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- Advice on safe handling : Do not get on skin or clothing.
 Do not breathe mist or vapors.
 Do not swallow.
 Avoid contact with eyes.
 Wash skin thoroughly after handling.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 Keep container tightly closed.
 Do not eat, drink or smoke when using this product.
 Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
 When using do not eat, drink or smoke.
 Wash contaminated clothing before re-use.
 The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- Conditions for safe storage : Keep in properly labeled containers.
 Store locked up.
 Keep tightly closed.
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
 Strong oxidizing agents
 Organic peroxides
 Explosives
 Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Testosterone	58-22-0	TWA	1 µg/m ³ (OEB 4)	Internal
		Wipe limit	10 µg/100cm ²	Internal

- Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
 Essentially no open handling permitted.
 Use closed processing systems or containment technologies.
 If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or

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Filter type	:	exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Hand protection	:	Combined particulates and organic vapor type
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
Eye protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	:	Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	oily
Color	:	Colorless to pale yellow
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available

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Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:**Testosterone:**

Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute toxicity (other routes of	:	LDLo (Rat): 326 mg/kg

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administration) Application Route: Intraperitoneal

LD50 (Mouse): > 1,000 mg/kg
Application Route: Intraperitoneal

Skin corrosion/irritation

Causes mild skin irritation.

Components:**Testosterone:**

Method	:	No information available.
Result	:	Mild skin irritation
Remarks	:	largely based on human evidence

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Components:**Testosterone:**

Genotoxicity in vitro	:	Remarks: In vitro tests did not show mutagenic effects
Genotoxicity in vivo	:	Remarks: In vivo tests did not show mutagenic effects

Carcinogenicity

May cause cancer.

Components:**Testosterone:**

Result	:	May cause cancer after repeated exposure.
Remarks	:	IARC: (International Agency for Research on Cancer)
Carcinogenicity - Assessment	:	Sufficient evidence of carcinogenicity in animal experiments

Reproductive toxicity

May damage fertility or the unborn child.

Components:**Testosterone:**

Effects on fertility	:	Test Type: Fertility/early embryonic development
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Species: Rat
Application Route: Subcutaneous
Early Embryonic Development: LOAEL: 10 mg/kg body weight
Symptoms: Increase of total resorptions.
Remarks: Significant toxicity observed in testing

Test Type: Fertility
Species: Mouse
Application Route: Subcutaneous
Fertility: LOAEL: 80 µg/kg
Target Organs: male reproductive organs, Testis
Remarks: Significant toxicity observed in testing

Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: LOAEL: 300 µg/kg
Target Organs: male reproductive organs, Seminal vesicle, Testis
Remarks: Testicular atrophy
Significant toxicity observed in testing

Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: LOAEL: 50 µg/kg
Target Organs: Prostate, Testis
Result: Effects on mating performance

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Testis) through prolonged or repeated exposure.

Components:**Testosterone:**

Target Organs : Testis
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Testosterone:**

Species : Baboon
LOAEL : 8 mg/kg
Application Route : Intramuscular
Target Organs : Prostate
Remarks : May cause damage to organs.

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Species	: Rabbit
LOAEL	: 6 mg/kg
Application Route	: Intramuscular
Target Organs	: Mammary gland, Uterus (including cervix)
Remarks	: Adverse effects were observed in females only. May cause damage to organs.

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Testosterone:**

General Information	: Target Organs: male reproductive organs Symptoms: The most common side effects are:, Erythema, Headache, Inflammation, Liver effects, erectile dysfunction, hair loss
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SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Testosterone:**

Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 6.2 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility.
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LC50 (Acartia tonsa): 5.6 mg/l
Exposure time: 48 h

Toxicity to fish (Chronic toxicity)	: NOEC (Gasterosteus aculeatus (threespine stickleback)): < 0.08 µg/l Exposure time: 21 Days
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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia): 0.15 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
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NOEC (Daphnia): 2.5 mg/l
Exposure time: 7 d

Persistence and degradability

No data available

Bioaccumulative potential**Components:****Testosterone:**

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Partition coefficient: n-octanol/water : log Pow: 3.32
pH: 7

Mobility in soil

Components:

Testosterone:

Distribution among environmental compartments : log Koc: 3.34
Stability in soil :

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Testosterone, lauric acid, monoester with propane-1,2-diol)
Class : 9
Packing group : III
Labels : 9

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(Testosterone, lauric acid, monoester with propane-1,2-diol)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Testosterone, lauric acid, monoester with propane-1,2-diol)
Class : 9

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Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation**NOM-002-SCT**

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Testosterone, lauric acid, monoester with propane-1,2-diol)
Class	:	9
Packing group	:	III
Labels	:	9

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA

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- International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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