

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Testosterone Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 23.03.2020
1.2	10.10.2020	5331585-00003	Date of first issue: 26.11.2019

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

#### 1.1 Product identifier

Trade name : Testosterone Formulation

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

Use of the Sub-  
stance/Mixture : Pharmaceutical

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

Company : MSD  
Shotton Lane  
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00

Telefax : 908-735-1496

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Carcinogenicity, Category 1B	H350: May cause cancer.
Reproductive toxicity, Category 1B	H360: May damage fertility or the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H350 May cause cancer.  
H360 May damage fertility or the unborn child.

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H372 Causes damage to organs through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

### Prevention:

P201 Obtain special instructions before use.

P264 Wash skin thoroughly after handling.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

Testosterone

### 2.3 Other hazards

None known.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
lauric acid, monoester with propane-1,2-diol	27194-74-7 248-315-4	Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 1	>= 30 - < 50
Testosterone	58-22-0 200-370-5	Carc. 1B; H350 Repr. 1B; H360 STOT RE 1; H372 (Testis) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 1.000	>= 10 - < 20

For explanation of abbreviations see section 16.

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### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- |                            |   |   |
|----------------------------|---|---|
| General advice             | : | In the case of accident or if you feel unwell, seek medical advice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice.  |
| 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).                               |
| If inhaled                 | : | If inhaled, remove to fresh air.<br>Get medical attention.  |
| In case of skin contact    | : | In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.  |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |

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

- |       |   |   |
|-------|---|---|
| Risks | : | May cause cancer.<br>May damage fertility or the unborn child.<br>Causes damage to organs through prolonged or repeated exposure. |
|-------|---|---|

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

- |           |   |   |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

- |                                |   |  |
|--------------------------------|---|--|
| Suitable extinguishing media   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
| Unsuitable extinguishing media | : | None known.  |

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

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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.

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## SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

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.

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

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
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.

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

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
Gases

#### 7.3 Specific end use(s)

- Specific use(s) : No data available

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Testosterone	58-22-0	TWA	1 µg/m3 (OEB 4)	Internal

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		Wipe limit	10 µg/100cm <sup>2</sup>	Internal
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### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
lauric acid, monoester with propane-1,2-diol	Workers	Inhalation	Long-term systemic effects	12,3 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	3,5 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	2,18 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	1,25 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	1,25 mg/kg bw/day

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
lauric acid, monoester with propane-1,2-diol	Fresh water	0,068 µg/l
	Freshwater - intermittent	0,68 µg/l
	Marine water	0,0068 µg/l
	Marine water - intermittent	0,068 µg/l
	Sewage treatment plant	5,6 mg/l

## 8.2 Exposure controls

### 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

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.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

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Respiratory protection	:	contaminated clothing. If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

### SECTION 9: Physical and chemical properties

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

Appearance	:	oily
Colour	:	Colorless to pale yellow
Odour	:	No data available
Odour 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
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive

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Oxidizing properties : The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : Not applicable

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### **lauric acid, monoester with propane-1,2-diol:**

Acute oral toxicity : LD50 (Rat, female): > 2.000 mg/kg  
Method: OECD Test Guideline 420  
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg



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Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal toxicity

### Testosterone:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute toxicity (other routes of administration) : LDLo (Rat): 326 mg/kg  
Application Route: Intraperitoneal

LD50 (Mouse): > 1.000 mg/kg  
Application Route: Intraperitoneal

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### lauric acid, monoester with propane-1,2-diol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

### 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.

### Components:

#### lauric acid, monoester with propane-1,2-diol:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : No eye irritation  
Remarks : Based on data from similar materials

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

#### lauric acid, monoester with propane-1,2-diol:

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Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse
Method	: OECD Test Guideline 429
Result	: negative

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### **lauric acid, monoester with propane-1,2-diol:**

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative
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	Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Remarks: Based on data from similar materials
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	Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials
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##### **Testosterone:**

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

##### **lauric acid, monoester with propane-1,2-diol:**

Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Method: OECD Test Guideline 414
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Remarks: Based on data from similar materials

### Testosterone:

Effects on fertility

: Test Type: Fertility/early embryonic development  
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 through prolonged or repeated exposure.

### Components:

#### Testosterone:

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

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### Repeated dose toxicity

#### Components:

##### **lauric acid, monoester with propane-1,2-diol:**

Species	: Rat, male
NOAEL	: > 100 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days
Method	: OECD Test Guideline 408
Remarks	: Based on data from similar materials

##### **Testosterone:**

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

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

### 12.1 Toxicity

#### Components:

##### **lauric acid, monoester with propane-1,2-diol:**

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): > 3,1 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0,6 mg/l Exposure time: 48 h Method: OECD Test Guideline 202

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Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0,068 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,033 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 10

Toxicity to microorganisms : EC50 : > 100 mg/l  
Exposure time: 3 h  
Method: OECD Test Guideline 209  
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1

### 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

LC50 (Acartia tonsa): 5,6 mg/l  
Exposure time: 48 h

Toxicity to fish (Chronic toxicity) : NOEC: < 0,08 µg/l  
Exposure time: 21 Days  
Species: Gasterosteus aculeatus (threespine stickleback)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,15 mg/l  
Exposure time: 21 d  
Species: Daphnia (water flea)  
Method: OECD Test Guideline 211

NOEC: 2,5 mg/l  
Exposure time: 7 d  
Species: Daphnia (water flea)

M-Factor (Chronic aquatic toxicity) : 1.000

## 12.2 Persistence and degradability

### Components:

#### **lauric acid, monoester with propane-1,2-diol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 94 %  
Exposure time: 28 d

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Method: OECD Test Guideline 301F

### 12.3 Bioaccumulative potential

#### Components:

##### **lauric acid, monoester with propane-1,2-diol:**

Partition coefficient: n-octanol/water	:	log Pow: > 4
Remarks: Expert judgement		

##### **Testosterone:**

Partition coefficient: n-octanol/water	:	log Pow: 3,32
		pH: 7

### 12.4 Mobility in soil

#### Components:

##### **Testosterone:**

Distribution among environmental compartments	:	log Koc: 3,34
Stability in soil	:	

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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

### 14.1 UN number

ADN	:	UN 3082
ADR	:	UN 3082
RID	:	UN 3082
IMDG	:	UN 3082
IATA	:	UN 3082

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### 14.2 UN proper shipping name

<b>ADN</b>	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Testosterone, lauric acid, monoester with propane-1,2-diol)
<b>ADR</b>	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Testosterone, lauric acid, monoester with propane-1,2-diol)
<b>RID</b>	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Testosterone, lauric acid, monoester with propane-1,2-diol)
<b>IMDG</b>	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Testosterone, lauric acid, monoester with propane-1,2-diol)
<b>IATA</b>	:	Environmentally hazardous substance, liquid, n.o.s. (Testosterone, lauric acid, monoester with propane-1,2-diol)

### 14.3 Transport hazard class(es)

<b>ADN</b>	:	9
<b>ADR</b>	:	9
<b>RID</b>	:	9
<b>IMDG</b>	:	9
<b>IATA</b>	:	9

### 14.4 Packing group

<b>ADN</b>	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
<b>ADR</b>	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)
<b>RID</b>	
Packing group	: III
Classification Code	: M6
Hazard Identification Number	: 90
Labels	: 9
<b>IMDG</b>	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
<b>IATA (Cargo)</b>	
Packing instruction (cargo aircraft)	: 964

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Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

## 14.6 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.

## 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	: Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	: Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	: Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import	: Not applicable



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Testosterone Formulation

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of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

### The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

### Full text of H-Statements

H350 : May cause cancer.  
H360 : May damage fertility or the unborn child.  
H372 : Causes damage to organs through prolonged or repeated exposure.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

### Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Carc. : Carcinogenicity  
Repr. : Reproductive toxicity  
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concen-

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tration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

### Further information

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

### Classification of the mixture:

Carc. 1B	H350
Repr. 1B	H360
STOT RE 1	H372
Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NO / EN