

# Testosteronum

## Safety Data Sheet

**400955**

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 2.0

Date of issue: 29/04/2014 Revision date: 15/02/2017

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

#### 1.1. Product identifier

Product form : Substance  
 Substance name : Testosteronum  
 IUPAC name : 17-hydroxyandrost-4-en-3-one  
 EC No : 200-370-5  
 CAS No : 58-22-0  
 Product code : 400955  
 Formula : C19H28O2  
 Synonyms : MICRONISATUM; Testosteron (microbiological origin)

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

##### 1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry  
 Industrial/Professional use spec : Industrial  
 For professional use only

##### 1.2.2. Uses advised against

No additional information available

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

##### Supplier

Duchefa Farma BV  
 A. Hofmanweg 71  
 2031BH Haarlem - Nederland  
 T +31(0)23-5319093  
[farma@duchefa.nl](mailto:farma@duchefa.nl) - [www.duchefa-farma.com](http://www.duchefa-farma.com)

#### 1.4. Emergency telephone number

Emergency number : Supplier contact information:  
 +31(0)23-5319093 (M-F 09:00-17:00)  
 +31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

### SECTION 2: Hazards identification

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

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 4 H302  
 Carcinogenicity, Category 2 H351

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Reproductive toxicity, Category 1A H360  
Specific target organ toxicity — Repeated exposure, Category 1 H372

Full text of hazard classes and H-statements : see section 16

### Adverse physicochemical, human health and environmental effects

No additional information available

## 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07 GHS08

Signal word (CLP) : Danger

Hazard statements (CLP) : H302 - Harmful if swallowed  
H351 - Suspected of causing cancer  
H360 - May damage fertility or the unborn child  
H372 - Causes damage to organs through prolonged or repeated exposure

Precautionary statements (CLP) : P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required  
P308+P313 - IF exposed or concerned: Get medical advice/attention

## 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type : Pharmaceuticals

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Testosteronum	(CAS No) 58-22-0 (EC No) 200-370-5	100	Acute Tox. 4 (Oral), H302 Carc. 2, H351 Repr. 1A, H360 STOT RE 1, H372

Full text of H-statements: see section 16

### 3.2. Mixtures

Not applicable

## 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 exposed or concerned: Get medical advice/attention. May cause cancer.

First-aid measures after inhalation : Assure fresh air breathing. Allow the victim to rest.

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- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists. Ensure adequate flushing of eyes by separating eyelids with the fingers.
- First-aid measures after ingestion : Rinse mouth. Obtain emergency medical attention. Call a POISON CENTER or doctor/physician if you feel unwell. Give water to drink. Induce vomiting (ONLY IN CONSCIOUS PERSONS!).

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

- Symptoms/injuries : May damage fertility. May damage the unborn child.
- Symptoms/injuries after ingestion : Swallowing a small quantity of this material will result in serious health hazard.

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

No additional information available

## SECTION 5: Fire-fighting measures

### 5.1. Extinguishing media

- Suitable extinguishing media : All extinguishing agents can be used. Making extinguishing agents environment-friendly.

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

- Fire hazard : Combustible.
- Hazardous decomposition products in case of fire : In case of fire hazardous gases / vapors may form: flue gas.

### 5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

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

- General measures : Avoid contact with skin and eyes. Do not breathe dust.

#### 6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

#### 6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

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

- Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

## 6.4. Reference to other sections

Reference to other sections (8, 13).

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Do not handle until all safety precautions have been read and understood.

Hygiene measures : Do not eat, drink or smoke when using this product.

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

Storage conditions : Keep container closed when not in use. Store in a dry place. Keep only in the original container in a cool, well-ventilated place.

Incompatible materials : Sources of ignition. Direct sunlight.

Storage temperature : 15 - 25 °C

### 7.3. Specific end use(s)

Pharmaceutical industry.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Personal protective equipment:

Avoid all unnecessary exposure.

#### Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

#### Eye protection:

Protective goggles. Safety glasses (to European standard EN 166 or equivalent)

#### Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck). Chemical resistant apron

#### Respiratory protection:

Approved dust respirator. Dustmask with filtertype P3

#### Other information:

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

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

Physical state : Solid

Colour : White.

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Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 152 - 154 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Poorly soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
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

Not established.

### 10.3. Possibility of hazardous reactions

Not established.

### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

In case of fire hazardous gases / vapors may form: flue gas.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

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<b>Testosteronum (58-22-0)</b>	
LD50 oral rat	1000 mg/kg
Skin corrosion/irritation	: Not classified
Additional information	: Repeated or prolonged skin contact may cause irritation
Serious eye damage/irritation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified
	Based on available data, the classification criteria are not met
Carcinogenicity	: Suspected of causing cancer.
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-repeated exposure	: Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Harmful if swallowed.

## SECTION 12: Ecological information

### 12.1. Toxicity

No additional information available

### 12.2. Persistence and degradability

<b>Testosteronum (58-22-0)</b>	
Persistence and degradability	Not established.

### 12.3. Bioaccumulative potential

<b>Testosteronum (58-22-0)</b>	
Bioaccumulative potential	Not established.

### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Other adverse effects

Additional information : Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of this material and its container at hazardous or special waste collection point.

Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
<b>14.1. UN number</b>	
Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>	
Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>	
Not applicable	Not applicable
Not applicable	Not applicable
<b>14.4. Packing group</b>	
Not applicable	Not applicable
<b>14.5. Environmental hazards</b>	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

### 14.6. Special precautions for user

#### - Overland transport

No data available

#### - Air transport

No data available

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

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Testosteronum is not on the REACH Candidate List

Testosteronum is not on the REACH Annex XIV List

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Skin and body protection	Modified	Added additional information (type of clothing related to concentration)

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### Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. **REACH Disclaimer:**  
This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number).

### Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Carc. 2	Carcinogenicity, Category 2
Repr. 1A	Reproductive toxicity, Category 1A
STOT RE 1	Specific target organ toxicity — Repeated exposure, Category 1
H302	Harmful if swallowed
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure

SDS EU (REACH Annex II) Version 2017

*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*