

 EURO OTC PHARMA® — Service mit Kompetenz und Substanz —	SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006 (REACH) according to Regulation (EU) No. 2020/878	Date: Page: Vers.-No.	24.07.2024 1 von 12 05
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Art.-Ref.: Testosterone, micronised

Art.-No.: 700277

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

1.1 Product identifier

Product name: Testosterone, micronised

Index-Nr.: -

EC-Nr.: 200-370-5

CAS-Nr.: 58-22-0

REACH- Registration number.: 01-2119937829-19-XXXX

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

Identified uses:

- Active pharmaceutical ingredient (API)

Uses advised against:

- Any use other than the active pharmaceutical ingredient (API)

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier

Euro OTC Pharma GmbH

Edisonstr. 6

59199 Bönen

Telephone / fax / E-Mail

- 02383 / 922020
- 02383 / 92202150
- info@euro-otc.com

1.4 Emergency telephone number

0361 / 730730 (Gemeinsames Giftnotrufzentrum, Nordhäuser Str. 74, 99089 Erfurt) (Germany)

ChemTel Contract Number MIS5311335 –

USA and Canada: +1-800-255-3924 (toll free),

Australia: +1-300-954-583,

Brazil: +0-800-591-6042,

China: +400-120-0751,

India: +000-800-100-4086,

Mexico: 800-099-0731,

International phone number: +1-813-248-0585 (collect calls accepted)

SECTION 2: Hazards identification:

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 (CLP/GHS)

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Acute Tox. 4: Harmful if swallowed.
Aquatic Acute 1: Very toxic to aquatic life.
Carc. 2: Suspected of causing cancer.
Lact.: May cause harm to breast-fed children.
Repr. 1A: May damage fertility or the unborn child.

2.2 Label elements

Label elements According to Regulation (EC) No 1272/2008

Hazard pictograms:



Signal word: Danger

Hazard statements:

H302	Harmful if swallowed.
H351	Suspected of causing cancer
H360FD	May damage fertility. May damage the unborn child.
H362	May cause harm to breast-fed children
H400	Very toxic to aquatic life

Precautionary statement(s)

P263	Avoid contact during pregnancy and while nursing
P273	Avoid release to the environment
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
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

- The substance is not PBT
- The substance is not vPvB
- Substance does not have endocrine disrupting properties.
- In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment

SECTION 3: Composition/information on ingredients

3.1 Substances

Main component of the fabric

Product/ingredient name: Testosterone, micronised

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EG-Nr.: 58-22-0

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CAS-Nr.: 200-370-5

Chemical formula: C₁₉H₂₈O₂

Molecular weight: 288,4

Purity: 100% [mass]

SECTION 4: First aid measures

4.1 Description of first aid measures

Delayed effects may occur after the exposure to the product.

General Advice

- Consult a physician. Show this safety data sheet to the doctor in attendance.

Inhalation:

- Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration.

Skin contact:

- Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

Eye contact:

- Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up and seek medical assistance.

If swallowed:

- If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed Over-exposure signs/symptoms

- Harmful Product, prolonged exposure due to inhalation may cause anaesthetic effects and the need for immediate medical assistance.
- Long-term chronic exposure may result in injury to certain organs or tissues.

4.3 Indication of any immediate medical attention and special treatment needed

- In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

- Extinguish with carbon dioxide, dry chemical, alcohol resistant foam or waterspray.

Unsuitable extinguishing media:

- Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

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5.2 Special hazards arising from the substance or mixture

- Exposure to combustion or decomposition products can be harmful to your health.

5.3 Advice for firefighters

- Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways. Product residues and extinguishing media may contaminate the aquatic environment.

Fire protection equipment

- According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

6. SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- For exposure control and individual protection measures, see section 8.

6.2 Environmental precautions

- Product dangerous for the environment, in case of large spills or if the product contaminates lakes, rivers, or sewers, inform the responsible authorities according to local legislation. Prevent the contamination of drains, surface or subterranean waters, and the ground.

6.3 Methods and materials for containment and cleaning up

- Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.
- Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

6.4 Reference to other sections

- For exposure control and individual protection measures, see section 8.
 - For later elimination of waste, follow the recommendations under section 13.
-

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- For personal protection, see section 8.
- In the application area, smoking, eating, and drinking must be prohibited.
- Follow legislation on occupational health and safety.
- Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

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7.2 Conditions for safe storage, including any incompatibilities

- Store according to local legislation. Observe indications on the label. Store the containers between 15 and 25 °C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorised persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

7.3 Specific end use(s)

- No further relevant information available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

8.2 Exposure controls

Appropriate engineering controls

- Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

Individual protection measures, such as personal protective equipment

Concentration	100 %
Uses:	Active pharmaceutical ingredient
Breathing protection:	
PPE:	Particle filter mask
Characteristics:	«CE» marking, category III. Made of filtering material, it covers nose, mouth and chin.
CEN standards:	EN 149
Maintenance:	Check for any tears, defects, etc. before use. Since it is disposable individual protection equipment, it should be replaced after use.
Observations:	Does not protect worker unless properly adjusted. Follow the manufacturer's instructions regarding suitable use of the equipment.
Filter Type needed:	P2
Hand protection:	
PPE:	Non-disposable protective gloves against chemicals.
Characteristics:	«CE» marking, category III. Check the list of chemicals for which the glove has been tested.
CEN standards:	EN 374-1, EN 374-2, EN 374-3, EN 420



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Maintenance:	A schedule for the periodical replacement of gloves should be established in order to guarantee their replacement before pollutants permeate them. The use of contaminated gloves could be more dangerous than not using gloves, since the pollutant can gradually accumulate in the glove's material.		
Observations:	They are to be replaced whenever tears, cracks or deformations are observed or when exterior dirt could reduce their strength.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.): > 480	Material thickness (mm): 0,35
Eye protection:			
PPE:	Protective goggles against particle impacts		
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
Skin protection:			
PPE:	Chemical protective clothing		
Characteristics:	«CE» marking, category III. Clothing should fit properly. The level of protection must be set according to a test parameter called BT (Breakthrough Time), which indicates how long it takes for the chemical to pass through the material.		
CEN standards:	EN 464, EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing's design should facilitate correct positioning, staying in place without moving for the period of use expected, bearing in mind environmental factors as well as any movement or position the user might adopt while carrying out the activity.		
PPE:	Anti-static safety footwear against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals against which the footwear is resistant.		
CEN standards:	EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345		
Maintenance:	For correct maintenance of this kind of safety footwear, it is necessary to observe the instructions specified by the manufacturer. The footwear should be replaced as soon as any sign of damage is observed.		
Observations:	The footwear should be cleaned regularly and dried when damp, although it should not be placed too close to a source of heat in order to avoid any sharp changes in temperature.		

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties Appearance

General Information

Physical state: Solid
Color: White

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Odor:	No information available
Odor threshold:	No information available
pH:	No information available
Melting point/freezing point:	–143-155°C
Initial boiling point and boiling range:	No information available
Flammability:	No information available
Flash point:	No information available
Evaporation rate	No information available
Lower and upper explosion limit:	No information available
Vapor pressure:	No information available
Vapor density:	No information available
Absolute density:	No information available
Relative Density (water=1)	No information available
Solubility(ies)	Insoluble in water
Hydrosolubility	No information available
Liposolubility	No information available
Partition coefficient: n-octanol/water:	No information available
Auto-ignition temperature:	No information available
Decomposition temperature:	No information available
Viscosity:	Not available

9.2 Other information

- Not applicable/Not available due to the nature/properties of the product

SECTION 10: Stability and reactivity

10.1 Reactivity

- The product does not present hazards by their reactivity

10.2 Chemical stability

- Stable under recommended storage conditions

10.3 Possibility of hazardous reactions

- No further relevant information available

10.4 Conditions to avoid:

- Avoid direct sunlight, and avoid forming dust fog to cause heat release

10.5 Incompatible materials:

- Strong oxidizing agents

10.6 Hazardous decomposition products

- Hazardous decomposition products formed under fire conditions. - Carbon oxides

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SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity-Ingestion

- No information available

Carcinogenicity

Product classified:

- Carcinogen, Category 1B: May cause cancer.

Reproductive toxicity

Product classified:

- Reproductive toxicant, Category 2: Suspected of damaging fertility or the unborn child.

Skin corrosion/irritation

- May be harmful if absorbed through skin. May cause skin irritation

Serious eye damage/irritation

- May cause eye irritation

Skin sensitization

- No information available

Respiratory sensitization

- No information available

STOT-single exposure

- No information available

STOT-repeated exposure

- No information available

Inhalation hazard

- May be harmful if inhaled. May cause respiratory tract irritation

Germ cell mutagenicity

- No information available

Additional hazard of reproductive toxicity

- No information available

11.2 Information on other hazards

Endocrine disrupting properties

- This product does not contain components with endocrine-disrupting properties with effects on human health.

Other information

- There is no information available on other adverse health effects.

SECTION 12: Ecological information

12.1 Toxicity

No information is available regarding the ecotoxicity.

12.2 Persistence and degradability

No information is available regarding the biodegradability

No information is available on the degradability

No information is available about persistence and degradability of the product.

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12.3 Bioaccumulative potential

Name	Log Pow	BCF	NOECs	Level
Testosterone CAS No: 58-22-0 EC No: 200-370-5	log Pow: 2.84	-	-	Verly low

12.4 Mobility in soil

- No information is available about the mobility in soil.
- The product must not be allowed to go into sewers or waterways.
- Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment

- No information is available about the results of PBT and vPvB assessment of the product.

12.6 Endocrine disrupting properties

- This product doesn't contain components with environmental endocrine disrupting properties.

12.7 Other adverse effects

- The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.
- No information is available about other adverse effects for the environment.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.
- Follow the provisions of Directive 2008/98/EC regarding waste management.

SECTION 14: Transport information

14.1 UN number or ID number

- UN3077

14.2 UN proper shipping name

ADR, IMDG

- UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (CONTAINS TESTOSTERONE), 9, PG III, (-)

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IATA

- UN 3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (CONTAINS TESTOSTERONE), 9, PG

14.3 Transport Hazard Class:

- 9

14.4 Packing Group

- III

14.5 Environmental hazards:

Marine pollutant:

Yes



- Dangerous for the environment
- Transport by ship, FEm – Emergency sheets (F – Fire, S - Spills): F-A,S-F

14.6 Special precautions for user

- Labels: 9



- Hazard number: 90
- Provisions concerning carriage in bulk ADR:
- VC1: Carriage in bulk in sheeted vehicles, sheeted containers or sheeted bulk containers is permitted.
- VC2 :Carriage in bulk in closed vehicles, closed containers or closed bulk containers is permitted.
- Proceed in accordance with point 6.
- ADR LQ: 5 kg
- IMDG LQ: 5 kg
- ICAO LQ: 30 kg B

14.7 Transport in bulk according to Annex 11 of MARPOL and the IBC code

- The product is not transported in bulk.

SECTION 15: Regulatory information

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

- The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

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- The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

15.2 Chemical Safety Assessment

- No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.
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SECTION 16: Other information

Classification codes:

- Acute Tox. 4: Acute toxicity (Oral), Category 4
- Aquatic Acute 1: Acute toxicity to the aquatic environment, Category 1
- Carc. 2: Carcinogen, Category 2
- Lact.: Effects on or via lactation
- Repr. 1A: Reproductive toxicant, Category 1A

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

- **Physical hazards:** On basis of test data
- **Health hazards:** Calculation method
- **Environmental hazards:** Calculation method
- It is advisable to carry out basic training regarding health and safety at work in order to handle this product correctly

Contact person: Mr. Dr. Abdulsalam Adam

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ARD: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
LC₅₀: Lethal concentration, 50 percent
LD₅₀ Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

Key literature references and sources for data:

- <http://eur-lex.europa.eu/homepage.html>
- <http://echa.europa.eu/>
- Regulation (EU) 2020/878.
- Regulation (EC) No 1907/2006.
- Regulation (EC) No 1272/2008.

The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemical substances and mixtures (REACH)

The above information is based on the current state of our knowledge and experience. They describe the products with regard to safety requirements and do not represent a guarantee of properties. The recipient of our product is responsible for observing existing laws and regulations.