

Page 1/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 17.03.2023 Version number 1.00 Revision: 17.03.2023

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

· Product identifier

· Trade name: Testosterone, micronized, API

· Article number: 2682

· CAS Number:

58-22-0

· EC number:

200-370-5

- · Registration number The substance is exempt from REACH-registration.
- Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

- · Uses advised against No relevant information available.
- Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

CAELO

Caesar & Loretz GmbH

Herderstr. 31

D-40721 Hilden

GERMANY

· Further information obtainable from:

E-mail: info@caelo.de

Tel.: +49210349940 (during regular opening hours)

Emergency telephone number:

Poison Information Center Bonn Venusberg-Campus 1, 53127 Bonn

Tel: +49 (0) 228-192400

2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Acute Tox. 4 H302 Harmful if swallowed.

Carc. 2 H351 Suspected of causing cancer.

Repr. 1B H360 May damage fertility or the unborn child.

Aquatic Acute 1 H400 Very toxic to aquatic life.

· Label elements

· Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

(Contd. on page 2)



Page 2/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 17.03.2023 Version number 1.00 Revision: 17.03.2023

Trade name: Testosterone, micronized, API

(Contd. of page 1)

· Hazard pictograms



- Signal word Danger
- Hazard statements

H302 Harmful if swallowed.

H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.

H400 Very toxic to aquatic life.

Precautionary statements

P273 Avoid release to the environment.

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

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth. P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

- · Other hazards
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- Determination of endocrine-disrupting properties Not applicable.

3 Composition/information on ingredients

- · Substances
- · CAS No. Description

CAS: 58-22-0 testosterone

- · Identification number(s)
- EC number: 200-370-5

4 First aid measures

- · Description of first aid measures
- · General information: Seek medical treatment in case of complaints.
- · After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

- · After skin contact: Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

(Contd. on page 3)



Page 3/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 17.03.2023 Version number 1.00 Revision: 17.03.2023

Trade name: Testosterone, micronized, API

(Contd. of page 2)

· After swallowing:

Rinse mouth with plenty of water.

Call a doctor immediately.

Most important symptoms and effects, both acute and delayed

No further relevant information available.

Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

All regular extinguishing media can be used.

Use fire extinguishing methods suitable to surrounding conditions.

Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Carbon monoxide (CO)

Carbon dioxide (CO2)

- · Advice for firefighters
- Protective equipment: In case of fire wear suitable protective clothes and respiratory protection.
- · Additional information

Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Use respiratory protective device against the effects of fumes/dust/aerosol.

Ensure adequate ventilation

- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Take up dry.

Dispose contaminated material as waste according to item 13.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

- · Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- · Storage
- · Requirements to be met by storerooms and receptacles:

Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

- Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Protect from exposure to the light.

(Contd. on page 4)



Page 4/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 17.03.2023 Version number 1.00 Revision: 17.03.2023

Trade name: Testosterone, micronized, API

(Contd. of page 3)

· Storage class:

TRHS 510: 6.1 D non-combustible acutely toxic substances or substances with chronic effects

· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Store protective clothing separately.

- Respiratory protection: Dust protection mask.
- · Hand protection Protective gloves
- · Material of gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- · Eye/face protection Tightly sealed goggles
- · Body protection: Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

Physical state
Colour:
Odour:
Odourless
Odour threshold:
Melting point/freezing point:
143–155 °C

· Boiling point or initial boiling point and boiling

range Undetermined.

• Flammability Product is not flammable.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.
pH Not applicable.

(Contd. on page 5)



Page 5/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 17.03.2023 Version number 1.00 Revision: 17.03.2023

Trade name: Testosterone, micronized, API

(Contd. of page 4)

· Viscosity:

Kinematic viscosity Not applicable. · Dynamic: Not applicable.

· Solubility

· water at 20 °C: < 0.1 g/I

· Partition coefficient n-octanol/water (log value) Not determined. · Vapour pressure: Not applicable.

· Density and/or relative density

· Density at 20 °C: 1.18 g/cm³ Relative density Not determined. · Vapour density Not applicable. · Particle characteristics Not determined

· Other information

· Appearance:

· Form: Crystalline

· Important information on protection of health

and environment, and on safety.

· Auto-ignition temperature: Not determined.

Explosive properties: Product does not present an explosion hazard.

· Change in condition

· Evaporation rate Not applicable.

· Information with regard to physical hazard

classes

· Explosives Void Void · Flammable gases Void Void

· Aerosols Void

Void · Oxidising gases Void

Void · Gases under pressure Void Void · Flammable liquids Void

Void · Flammable solids Void

Void · Self-reactive substances and mixtures Void

Void · Pyrophoric liquids Void Void

· Pyrophoric solids Void Void

· Self-heating substances and mixtures Void Void

(Contd. on page 6)



Page 6/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 17.03.2023 Version number 1.00 Revision: 17.03.2023

Trade name: Testosterone, micronized, API

(Contd. of page 5)

· Substances and mixtures, which emit flammable	•
gases in contact with water	Void
	Void
· Oxidising liquids	Void
	Void
· Oxidising solids	Void
-	Void
· Organic peroxides	Void
-	Void
· Corrosive to metals	Void
	Void
Desensitised explosives	Void
·	Void

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: Oxidizing agent
- · Hazardous decomposition products:

Carbon monoxide Carbon dioxide

11 Toxicological information

- Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Harmful if swallowed.
- LD/LC50 values relevant for classification:

Oral LD50 500 mg/kg (rat)

Dermal LD50 2,000 mg/kg (rat)

- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity 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 Based on available data, the classification criteria are not met.
- STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- · Information on other hazards
- · Endocrine disrupting properties

On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

(Contd. on page 7)



Page 7/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 17.03.2023 Version number 1.00 Revision: 17.03.2023

Trade name: Testosterone, micronized, API

(Contd. of page 6)

12 Ecological information

- · Toxicity
- · Aquatic toxicity:

ErC50 0.7 mg/L /72h (Algae: desmodesmus subspicatus)

- · Persistence and degradability Easily biodegradable
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Endocrine disrupting properties

Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.

The product does not contain substances with endocrine disrupting properties.

- · Other adverse effects
- · Additional ecological information:
- **General notes:**

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.

13 Disposal considerations

- · Waste treatment methods
- Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- **Recommendation:** Disposal must be made according to local regulations.

14 Transport information

· UN number or ID number

· ADR, IMDG, IATA UN3077

· UN proper shipping name

· ADR 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S. (testosterone)

·IMDG ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S. (testosterone)

·IATA Environmentally hazardous substance, solid, n.o.s.

(testosterone)

· Transport hazard class(es)

· ADR, IMDG, IATA

· Class 9 Miscellaneous dangerous substances and articles. 9

· Label

(Contd. on page 8)



Page 8/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 17.03.2023 Version number 1.00 Revision: 17.03.2023

Trade name: Testosterone, micronized, API

(Contd. of page 7)

· Packing group

· ADR. IMDG. IATA

· Environmental hazards:

Marine pollutant:
 Special marking (ADR):
 Special marking (IATA):
 Symbol (fish and tree)
 Symbol (fish and tree)

Special precautions for user Warning: Miscellaneous dangerous substances and

articles.

· Hazard identification number (Kemler code): 90

· EMS Number: F-A,S-F

· Maritime transport in bulk according to IMO

instruments Not applicable.

· Transport/Additional information:

· ADR

Limited quantities (LQ)
 Transport category
 Tunnel restriction code
 (-)

· IMDG

· Limited quantities (LQ) 5 kg

· UN "Model Regulation": UN 3077 ENVIRONMENTALLY HAZARDOUS

SUBSTANCE, SOLID, N.O.S. (TESTOSTERONE), 9, III

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV) Not listed
- REGULATION (EC) No 1907/2006 ANNEX XVII Not listed
- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Annex II

Substance is not listed.

- · National regulations:
- · Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)

TRHS 510: 6.1 D non-combustible acutely toxic substances or substances with chronic effects

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.

- · Reasons for alterations This version replaces all old versions.
- Date of previous version: 17.03.2023
- Abbreviations and acronyms:

ADR: Accord relatif au transport international 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

(Contd. on page 9)



Page 9/9

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 17.03.2023 Version number 1.00 Revision: 17.03.2023

Trade name: Testosterone, micronized, API

(Contd. of page 8)

CAS: Chemical Abstracts Service (division of the American Chemical Society)

MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Acute Tox. 4: Acute toxicity – Category 4 Carc. 2: Carcinogenicity – Category 2

Repr. 1B: Reproductive toxicity – Category 1B
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

* Data compared to the previous version altered.

IE —