



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

Printing date 31.03.2023

Version number 1.00

Revision: 31.03.2023

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

- **Product identifier**
- **Trade name:** Norethisterone acetate, API
- **Article number:** 4489
- **CAS Number:**
51-98-9
- **EC number:**
200-132-0
- **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**

Carc. 2	H351	Suspected of causing cancer.
Repr. 1A	H360FD-H362	May damage fertility. May damage the unborn child. May cause harm to breast-fed children.
Aquatic Acute 1	H400	Very toxic to aquatic life.
Aquatic Chronic 1	H410	Very toxic to aquatic life with long lasting effects.
- **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)

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

Printing date 31.03.2023

Version number 1.00

Revision: 31.03.2023

Trade name: Norethisterone acetate, API

(Contd. of page 1)

Hazard pictograms

GHS08



GHS09

Signal word Danger**Hazard statements**

H351 Suspected of causing cancer.

H360FD-H362 May damage fertility. May damage the unborn child. May cause harm to breast-fed children.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P260 Do not breathe dusts or mists.

P263 Avoid contact during pregnancy and while nursing.

P273 Avoid release to the environment.

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

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: 51-98-9 Norethisterone acetate

Identification number(s)**EC number:** 200-132-0

4 First aid measures

Description of first aid measures**After inhalation:** Supply fresh air; consult doctor in case of complaints.**After skin contact:** Generally the product does not irritate the skin.**After eye contact:** Rinse opened eye for several minutes under running water.**After swallowing:** If symptoms persist consult doctor.**Most important symptoms and effects, both acute and delayed**

No further relevant information available.

(Contd. on page 3)



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

Printing date 31.03.2023

Version number 1.00

Revision: 31.03.2023

Trade name: Norethisterone acetate, API

(Contd. of page 2)

- **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**
Combustible but not oxidising. In case of fire dangerous vapours/gases can be generated: Smoke gases.
- **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.
Avoid contact with the substance.
- **Environmental precautions:**
Do not allow to enter sewers/ surface or ground water.
Inform respective authorities in case of seepage into water course or sewage system.
- **Methods and material for containment and cleaning up:**
Take up dry. Clean up with water.
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** No special precautions are necessary if used correctly.
- **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:** No further information
- **Storage class:** TRHS 510: 6.1 C Combustible acutely toxic or chronic substances
- **Specific end use(s)** No further relevant information available.

(Contd. on page 4)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.03.2023

Version number 1.00

Revision: 31.03.2023

Trade name: Norethisterone acetate, API

(Contd. of page 3)

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.
- **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** Solid
- **Colour:** White
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** 158–164 °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.
- **Viscosity:**
- **Kinematic viscosity** Not applicable.
- **Dynamic:** Not applicable.

(Contd. on page 5)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.03.2023

Version number 1.00

Revision: 31.03.2023

Trade name: Norethisterone acetate, API

(Contd. of page 4)

· Solubility	
· water:	Not determined.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not applicable.
· Density and/or relative density	
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Particle characteristics	Not determined
· Other information	
· Appearance:	
· Form:	Solid
· 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
· Substances and mixtures, which emit flammable gases in contact with water	Void Void

(Contd. on page 6)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.03.2023

Version number 1.00

Revision: 31.03.2023

Trade name: Norethisterone acetate, API

(Contd. of page 5)

- | | |
|----------------------------------|------|
| · 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:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
Oral LD50 >2,800 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. May damage the unborn child. May cause harm to breast-fed children.
- **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.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.

(Contd. on page 7)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.03.2023

Version number 1.00

Revision: 31.03.2023

Trade name: Norethisterone acetate, API

(Contd. of page 6)

- **Persistence and degradability** No further relevant information available.
- **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**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): 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.
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms

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 | Not subject to transport regulations. |
| · ADR, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · ADR | not regulated |
| | 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
SOLID, N.O.S. (Norethisterone acetate) |
| · IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · ADR, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · ADR, IMDG, IATA | not regulated |
| · Environmental hazards: | |
| · Marine pollutant: | Symbol (fish and tree) |
| · Special marking (ADR): | Symbol (fish and tree) |
| · Special marking (IATA): | Symbol (fish and tree) |

(Contd. on page 8)



Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 31.03.2023

Version number 1.00

Revision: 31.03.2023

Trade name: Norethisterone acetate, API

(Contd. of page 7)

- **Special precautions for user** Not applicable.
- **Maritime transport in bulk according to IMO instruments** Not applicable.
- **UN "Model Regulation":** UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (NORETHISTERONE ACETATE), 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 nonstationary vessels (TRGS 510) (Germany)**
TRGS 510: 6.1 C Combustible acutely toxic or chronic substances
- **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:** 31.03.2023
- **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
 - CAS: Chemical Abstracts Service (division of the American Chemical Society)
 - MAL-Code: Måleteknisk Arbejdshygienisk 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
 - Carc. 2: Carcinogenicity – Category 2
 - Repr. 1A: Reproductive toxicity – Category 1A
 - Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
 - Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
- *** Data compared to the previous version altered.**