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

· **Informations to product No. 4489**

· **Product name:**

Norethisteronacetat, API Norethisteroni acetat

· **Supplier of the Product / responsible Company:**

Caesar & Loretz GmbH

Herderstr. 31

40721 Hilden

Tel.: 02103/4994-0

Fax: 02103/32360

e-mail: info@caelo.de

· **Emergency telephone:**

Giftinformationszentrum Mainz

Langenbeckstr. 1, 55131 Mainz

Tel.: 06131/19240

· **Relevant identified uses of the substance or mixture and uses advised against:**

No further relevant information available.

· **Application of the substance / mixture:**

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

2 Hazards identification

· **GHS-Labeling Elements:**



· **Signal word:** Danger

· **H-Phrases:**

H351 Suspected of causing cancer

H360FD May damage fertility or the unborn child

H362 May cause harm to breast-fed children

H410 Very toxic to aquatic life with long lasting effects

· **P-Phrases:**

P263 Avoid contact during pregnancy/while nursing

P260 Do not breathe dust/fume/gas/mist/vapours/spray

P273 Avoid release to the environment


P281 Use personal protective equipment as required

Carc. 2

Repr. 1A

Aquatic acute 1

Aquatic chronic 1

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3 Composition / information on ingredients

• **Chemical characterization:**

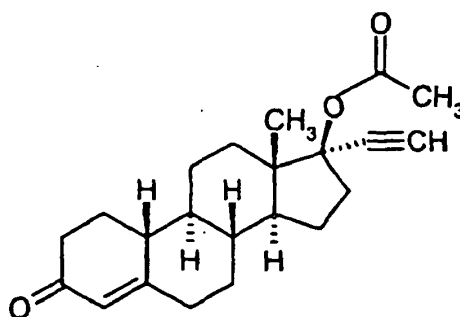
CAS-No. Substance name

51-98-9 Norethisterone acetate

• **EINECS-No.:** 200-132-0

• **REACH Reg. No.:** - (pre-registered)

• **INCI-Name:** -



4 First aid measures

- **after inhalation:** Fresh. If feeling unwell continuously seek medical advice.
- **after skin contact:** Take off contaminated clothes and shoes, wash immediately with plenty of water and soap.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open. Seek medical advice.
- **after swallowing:** Drink water. Induce vomiting. Seek medical advice.


5 Fire-fighting measures

- **Suitable extinguishing media:** All regular extinguishing media can be used. Select fire fighting measures suitable to surrounding environment.
- **Specific hazards during fire fighting:** Combustible but not flammable. In case of fire dangerous gases / vapours can be released: Smoke gases.
- **Special protective equipment for fire-fighters:** Suitable protective clothes and respiratory protection.
- **Additional information:** Prevent fire extinguishing water from contaminating surface water, the ground water system or soil. Residues must be deposited according to local regulations.

6 Accidental release measures

- **Personal protective measures:** Avoid dust formation and contact with substance.
- **Environmental protective measures:** Prevent from entering into drains.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

7 Handling and storage

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- **Handling:** No special requirements.
- **Storage:**
- **Requirements for storage areas and containers:**
Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).
- **Advices on common storage:**
TRGS 514 "Storage of toxic and very toxic substances ..."
- **Additional informations to storage conditions:** Keep container tightly closed.

8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **General protective and hygiene measures:**
Wash hands before breaks and after work.
Avoid contact with eyes and skin.
- **Respiratory protection:** Dust protection mask
- **Hand protection:** Protection gloves.
- **Eye protection:** Safety glasses.

9 Physical and chemical properties


- **Form:** solid
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 158 - 164 °C
- **Boiling point / boiling range:** not determined
- **Flammability (solid, vapours):** The product is not flammable.
- **Explosion hazard:** The product is not hazardous for explosion, but the explosion of dust-air mixtures is possible.
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** 44 mg/l (20 °C)

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:**
No decomposition during appropriate use.
- **Hazardous reactions:** No hazardous reactions known.
- **Hazardous decomposition products:** none

11 Toxicological information

- **Acute toxicity:**
LD50 (oral, rat): >2800 mg/kg
- **Sub-acute / chronic toxicity:**
There are sufficient signs that the product can impair human fertility. In animal experiments this properties had been proved.
The evaluation of a teratogenic effect is not yet finished
If this substance is consumed by breast-feeding women, harmful effects on the health of the child are

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possible.

- **Information on toxicological effects**
- **Primary irritant effect:**
- **on the skin:** irritant
- **on the eye:** irritant
- **on respiratory organs:** irritant
- **Carcinogenicity:** Limited evidence of a carcinogenic effect.

12 Ecological information

- **Ecotoxic effects:** Quantitative ecotoxicological data are not available.
- **Additional information:** Prevent from entering into environmental waters, waste water or soil. Danger for drinking water if even small quantities leak into the ground.
- **Water hazard class:** 2 (self classification): hazardous for water.

13 Disposal considerations

- **Product:**
- **Recommendation:** Disposal according to local regulations as pharmaceutical waste.
- **Empty contaminated packaging:**
- **Recommendation:** Disposal according to the local regulations.

14 Transport informations

- **Land transport according to ADR:**
Not classified as dangerous in the meaning of transport regulations.

15 Regulatory information

- **Labelling according to actual legislation (GHS, Globally Harmonized System of Classification and Labelling of Chemicals):**

The product is classified and labelled according to GHS-regulations.

- **Hazard symbols:** GHS08, GHS09

- **Signal word:** Danger

H351 Suspected of causing cancer

H360FD May damage fertility or the unborn child

H362 May cause harm to breast-fed children

H410 Very toxic to aquatic life with long lasting effects

- **P-Phrases:**

P263 Avoid contact during pregnancy/while nursing

P260 Do not breathe dust/fume/gas/mist/vapours/spray


P273 Avoid release to the environment

P281 Use personal protective equipment as required

- **National regulations (Germany):**

- **Water hazard class:** see chapter 12

- **Storage class TRGS 510:** 6.1C

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16 Other Information

The information provided in this MSDS is correct to the best of our knowledge at the date of edition.

· **Reason for last revision:** Adjustment to regulation (EC) 1907/2006 (REACH) and GHS-labelling system.