



**SAFETY DATA SHEET** according to EC 1907/2006

122000004145

**NORETHISTERONE**

Version 2.0

Revision Date 12.10.2010

Print Date 13.10.2010

**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**Product information**

NORETHISTERONE

REACH Registration Number: 01-2119455543-38-0000

Use : Active ingredient

**Company**

Bayer Schering Pharma AG  
Müllerstr. 178  
D-13342 BERLIN

Tel.: +49 (0) 214 30 46440

Mail: msds@bayerhealthcare.com

**In case of emergency:** +49 (0) 214 30 99300 (Sicherheitszentrale Bayer)

**2. HAZARDS IDENTIFICATION**

**GHS-Classification:**

Carcinogenicity, Category 2 (H351)  
Reproductive toxicity, Category 1A (H360FD)  
Effects on or via lactation (H362)

**GHS-Labeling:**



Danger

**Hazard statements:**

H351 Suspected of causing cancer.  
H360FD May damage fertility. May damage the unborn child.  
H362 May cause harm to breast-fed children.

**Precautionary statements:**

Prevention:

P281 Use personal protective equipment as required.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/attention.

Classification (67/548/EEC, 1999/45/EC)

Carcinogenic Category 3

Toxic to Reproduction Category 1

008587



**SAFETY DATA SHEET** according to EC 1907/2006  
**NORETHISTERONE**

122000004145

Version 2.0

Revision Date 12.10.2010

Print Date 13.10.2010

- 
- Toxic to Reproduction Category 2
- Limited evidence of a carcinogenic effect.
- May impair fertility.
- May cause harm to the unborn child.
- May cause harm to breastfed babies.
- 

**3. COMPOSITION/INFORMATION ON INGREDIENTS****Hazardous components**

Norethisterone  
Concentration [Weight percent] <= 100  
CAS-No.: 68-22-4  
CAS name: 19-Norpregn-4-en-20-yn-3-one, 17-hydroxy-, (17.alpha.)-  
EINECS-No.: 200-681-6  
Synonyms: Norethindron  
EU Classification: Carc.Cat.3, R40 Repr.Cat.1, R60 Repr.Cat.2, R61 R64  
GHS Classification: Carc. 2 H351 Repr. 1A H360FD Lact. H362  
For the full text of the R-phrases mentioned in this Section, see Section 16.

---

**4. FIRST AID MEASURES**

- General advice:** Take off contaminated clothing and shoes immediately. Call a physician immediately.
- If inhaled:** Remove to fresh air. If symptoms persist, call a physician.
- In case of skin contact:** After contact with skin, wash immediately with plenty of soap and water. Do NOT use solvents or thinners.
- In case of eye contact:** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
- If swallowed:** Rinse mouth with water.
- 

**5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media:** Water spray jet, Foam, Dry powder, Carbon dioxide (CO<sub>2</sub>)
- Unsuitable extinguishing media:** High volume water jet
- Specific hazards during fire fighting:** Fire may cause evolution of: Carbon dioxide (CO<sub>2</sub>) Carbon



**SAFETY DATA SHEET** according to EC 1907/2006  
**NORETHISTERONE**

122000004145

Version 2.0

Revision Date 12.10.2010

Print Date 13.10.2010

monoxide

**Special protective equipment for fire-fighters:** In the event of fire, wear self-contained breathing apparatus.

**Further information:** Prevent fire extinguishing water from contaminating surface water or the ground water system.

---

**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions:** Use personal protective equipment.

**Environmental precautions:** Do not flush into surface water or sanitary sewer system.

**Methods for cleaning up:** Use mechanical handling equipment. Avoid dust formation. Return contained product to the manufacturer. Flush with plenty of water.

**Additional advice:** Avoid dust formation.

---

**7. HANDLING AND STORAGE**

**Handling:**

Avoid contact with skin, eyes and clothing. Measures must be taken to prevent dust explosion when processing in fine crystalline form.

Take measures to prevent the build up of electrostatic charge. Keep away from open flames, hot surfaces and sources of ignition.

**Storage:**

Protect against light.

Storage class in accordance to VCI's Guide (May 2007): 6.1AS

---

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

Components with workplace control parameters

Substance	CAS-No.	Basis	Type:	Value	Ceiling Limit Value	Remarks
Norethisterone	68-22-4		OEL*	0.012 mg/m <sup>3</sup>		

\*OEL (BHC) = Occupational Exposure Limit, company threshold limit value (TLV)

**Respiratory protection:**

Recommended respiratory protection: full mask with filter P3

018869



**SAFETY DATA SHEET** according to EC 1907/2006  
**NORETHISTERONE**

122000004145

Version 2.0

Revision Date 12.10.2010

Print Date 13.10.2010

**Hand protection:**

During the handling of the substance according to the intended use protection gloves from nitrile rubber have been proved.

**Eye protection:**

Safety glasses with side-shields

**Skin and body protection:**

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

**Hygiene measures:**

Wash hands and face before breaks and immediately after handling the product. Use protective skin cream before handling the product.

**Other protective measures:**

Wear suitable protective equipment.

---

**9. PHYSICAL AND CHEMICAL PROPERTIES**

Form:	solid, crystalline
Colour:	off-white
Odour:	odourless
Melting point/range:	202 - 208 °C
Density:	no data available
Bulk density:	no data available
Vapour pressure:	< 0.001 mPa at 25 °C
Water solubility:	0.004 g/l at 20 °C practically insoluble
pH:	no data available
Partition coefficient (n-octanol/water):	log Pow: 2.66
Solubility in organic solvents:	no data available
Ignition temperature:	no data available

---

**10. STABILITY AND REACTIVITY**

**Conditions to avoid:** no data available

**Materials to avoid:** no data available

**Hazardous reactions:** Risk of dust explosion in fine crystalline powder form.

**Thermal decomposition:**

no data available



**SAFETY DATA SHEET** according to EC 1907/2006  
**NORETHISTERONE**

122000004145

Version 2.0

Revision Date 12.10.2010

Print Date 13.10.2010

**Hazardous decomposition products:**  
Carbon monoxide, Carbon dioxide (CO<sub>2</sub>)

**Minimum ignition energy:** < 5 mJ

**Dust explosion class:** St 3 (= very great danger of dust explosion)

**Further information:** The following applies in general to flammable organic substances and preparations: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

---

**11. TOXICOLOGICAL INFORMATION**

**Acute oral toxicity:**  
LD<sub>50</sub> mouse : > 12,000 mg/kg

LD<sub>50</sub> rat : > 2,800 mg/kg  
Test substance: data based on the acetate

**Pharmaceutical effects:**  
Hormone product

---

**12. ECOLOGICAL INFORMATION**

**General advice:**  
Do not allow to enter surface waters or groundwater.

**Toxicity to daphnia and other aquatic invertebrates:**  
EC<sub>50</sub> > 4.6 mg/l  
Test species: Daphnia Duration of test: 48 h

**Toxicity to bacteria:**  
EC<sub>50</sub> > 7.8 mg/l  
tested on: Pseudomonas putida  
Duration of test: 16 h

**Biodegradability:**  
Not readily biodegradable.

---

**13. DISPOSAL CONSIDERATIONS**

Transport to suitable incinerator with reduced non-air emission.

Contaminated, empty containers are to be treated in the same way as the contents.

---




**SAFETY DATA SHEET** according to EC 1907/2006  
**NORETHISTERONE**

122000004145

Version 2.0

Revision Date 12.10.2010

Print Date 13.10.2010

**14. TRANSPORT INFORMATION**

ADR/RID --

GGVS/GGVE --

ADNR --

IATA --

IMDG --

Other information : No dangerous cargo  
 Keep separated from foodstuffs

**15. REGULATORY INFORMATION****Labelling according to EC Directives:**

Labelling according to EC Directives

T Toxic

Hazardous components which must be listed on the label:

68-22-4 Norethisterone

R60 May impair fertility.  
 R61 May cause harm to the unborn child.  
 R40 Limited evidence of a carcinogenic effect.  
 R64 May cause harm to breastfed babies.  
 S53 Avoid exposure - obtain special instructions before use.  
 S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

TRGS 905

Carcinogenic Category 3

associated with reproductive risks category 1

embryotoxic (impairs embryonic development) category 2

**National legislation****Water contaminating class (Germany):** WGK 2 (water endangering)

VwVwS (German Regulation) supplement 3

**Guidelines and information sheets issued by the Chemical Industry Employers' Insurance Association:** M 053 /BGI 660 ("Protective measures when handling hazardous substances at work"), Employers' Liability Insurance Association leaflet (BGI) 5151, Working safely in the pharmaceutical industry (April 2009)., The recommendations given in the leaflet of the "Berufsgenossenschaft der Chemischen Industrie" (Employers' Liability Insurance Association for the German Chemical Industry) entitled "Fruchtschädigungen - Schutz am Arbeits-platz" (M 039) should be followed.

**Other regulations:** TRGS 500: Precaution: Least standards



**SAFETY DATA SHEET** according to EC 1907/2006  
**NORETHISTERONE**

122000004145

Version 2.0

Revision Date 12.10.2010

Print Date 13.10.2010

**16. OTHER INFORMATION**

**Full text of R-phrases referred to under sections 2 and 3**

R40	Limited evidence of a carcinogenic effect.
R60	May impair fertility.
R61	May cause harm to the unborn child.
R64	May cause harm to breastfed babies.

**Full text of H-Statements mentioned in chapters 2 and 3**

H351	Suspected of causing cancer.
H360FD	May damage fertility. May damage the unborn child.
H362	May cause harm to breast-fed children.

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

**Further information**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

018654

