



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

Safety Data Sheet (MSDS)

(According to GB/T 16483 and GB/T 17519; Adapts to GHS, IMDG, IATA Standards)

Product Name: Norethisterone

Product Number: NE-20260218

Brand: SIGALD

CAS Number: 68-22-4

Revision Date: 18 FEB 2026

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifiers

- Product Name: Norethisterone
- Synonyms: 17 α -Ethyne-19-nortestosterone; Norethindrone
- CAS-No.: 68-22-4
- Molecular Formula: C₂₀ H₂₆ O₂
- Molecular Weight: 298.42 g/mol

1.2 Details of the supplier of the safety data sheet

- Company: NEWAY SINOPHC TECH. LIMITED
- Address: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI)PILOT FREE TRADE ZONE.
- Telephone: +86-021-50350029
- Fax: +86-021-50350029

1.3 Emergency telephone

- Emergency Phone #: +86-021-50350029 (CHEMTREC)

1.4 Relevant Identified Uses and Uses Advised Against

- Identified Uses: Pharmaceutical raw material for contraceptive and gynecological drugs, research reagent, fine chemical intermediate for progestogen synthesis.
- Uses Advised Against: Not for human oral consumption without pharmaceutical formulation; not for unauthorized use; not for cosmetic use; not for release to the natural environment.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity (oral, rat): Category 4 (LD₅₀ = 2200 mg/kg)
- Reproductive toxicity: Category 1B
- Target organ toxicity (repeated exposure): Category 2 (endocrine system, liver)
- Hazard to the aquatic environment (long-term): Category 3

2.2 GHS Label Elements

- Hazard Pictograms: GHS07 (Exclamation mark), GHS08 (Health hazard), GHS09 (Environment)
- Signal Word: Danger
- Hazard Statements:
 - H302: Harmful if swallowed
 - H360: May damage fertility or the unborn child

- H373: May cause damage to organs (endocrine system, liver) through prolonged or repeated exposure
- H412: Harmful to aquatic life with long lasting effects
- Precautionary Statements:
- P201: Obtain special instructions before use
- P202: Do not handle until all safety precautions have been read and understood
- P264: Wash skin thoroughly after handling
- P270: Do not eat, drink or smoke when using this product
- P273: Avoid release to the environment
- P280: Wear protective gloves/eye protection/face protection
- P301+P312: If swallowed: Call a POISON CENTER/doctor if you feel unwell
- P308+P313: If exposed or concerned: Get medical advice/attention
- P391: Collect spillage
- P405: Store locked up
- P501: Dispose of contents/container to an approved waste disposal plant

2.3 Physical and Chemical Hazards: No physical or chemical hazards under normal use; combustible at high temperature (>300°C).

2.4 Health Hazards: Harmful if swallowed; reproductive toxicant; prolonged exposure may cause hormonal imbalance and liver function damage; no skin/eye irritation in normal handling.

2.5 Environmental Hazards: Harmful to aquatic life with long-lasting effects; low biodegradability and high bioaccumulation potential in aquatic organisms.

2.6 Other Hazards: No additional hazards identified.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: Pure Substance
- Active Ingredient: Norethisterone (100%, CAS:68-22-4)
- No hazardous impurities present above the specified limit values.

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately. If respiratory distress occurs, give oxygen and call a POISON CENTER/doctor at once.
- In Case of Skin Contact: Rinse the skin with plenty of soap and running water for at least 5 minutes. Remove contaminated clothing and wash it before reuse. No special treatment is needed if no irritation occurs.
- In Case of Eye Contact: Rinse eyes thoroughly with plenty of running water for 10-15 minutes, lifting the upper and lower eyelids occasionally. Consult a doctor if irritation or discomfort persists.
- If Swallowed: Do not induce vomiting. Rinse the mouth with water immediately. Call a POISON CENTER/doctor and provide the product MSDS for medical treatment.

4.2 Most Important Symptoms and Effects

- Acute Effects: Nausea, vomiting, abdominal pain after accidental ingestion; no obvious acute toxicity for skin and inhalation contact.
- Delayed Effects: Prolonged or repeated exposure may cause menstrual disorder, hormonal imbalance, liver function abnormalities and reproductive dysfunction.

4.3 Indication of Immediate Medical Attention

- Immediate medical attention is required for accidental ingestion, prolonged exposure or suspected reproductive system damage. Provide a copy of this MSDS to the attending physician.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, dry powder, foam, carbon dioxide (CO₂).
- Unsuitable Extinguishing Media: No limitations on extinguishing agents.

5.2 Special Hazards Arising from the Substance or Mixture

- The product is combustible at high temperature; burning may produce toxic fumes including carbon monoxide, carbon dioxide and hydrocarbon compounds.
- No explosion risk under normal use and storage conditions.

5.3 Advice for Firefighters

- Wear self-contained breathing apparatus (SCBA) and full fire-fighting protective gear when fighting fires.
- Fight the fire from a safe distance; prevent the fire runoff from entering water bodies to avoid environmental contamination.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

- Wear nitrile rubber gloves, safety glasses and N95 dust mask when handling the spillage.
- Avoid dust formation and inhalation; ensure good ventilation in the spill area.
- Evacuate non-essential personnel from the spill site to a safe area.

6.2 Environmental Precautions

- Strictly prevent the spillage from entering soil, sewers, rivers and other natural water bodies.
- Do not discharge the spilled material directly into the environment.

6.3 Methods and Materials for Containment and Cleaning Up

- Small Spill: Sweep up the spilled powder with a dry brush/spatula, collect it in a sealed hazardous waste container for proper disposal.
- Large Spill: Contain the spillage with sand or dikes, transfer the collected powder to a sealed container by vacuum with HEPA filter for disposal.

6.4 Reference to Other Sections: For the disposal of spilled waste, see Section 13.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling



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- Handle the product in a well-ventilated area with dust extraction equipment to avoid dust formation and inhalation.
- Wear the specified personal protective equipment (PPE) during all handling operations (see Section 8).
- Do not eat, drink, smoke or apply cosmetics when handling the product; wash hands and face thoroughly after handling.

- Avoid mixing the product with strong oxidizing agents, strong acids and strong bases.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

- Storage Conditions: Store in a cool, dry, dark place at 2-8°C, keep the container tightly sealed to avoid moisture and light.
- Storage Class: Dedicated chemical storage area for steroid pharmaceutical raw materials.
- Incompatibilities: Strong oxidizing agents, concentrated mineral acids, strong alkalis, halogenated compounds.
- Shelf Life: 24 months (unopened, under the specified storage conditions).
- Store locked up and separate from food, beverages, aquatic products and non-hazardous materials.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- No official occupational exposure limits (OEL) for Norethisterone; set the internal workplace limit of 0.1 mg/m³ for airborne dust.

8.2 Exposure Controls

- Engineering Controls: Install local exhaust ventilation (LEV) for dust-generating operations; conduct regular air quality monitoring.
- Personal Protective Equipment (PPE):
 - Eye/Face Protection: Chemical splash goggles and face shield for large-scale handling.
 - Skin Protection: Nitrile rubber gloves (thickness ≥0.3 mm), impermeable protective clothing and lab coat.
 - Respiratory Protection: N95 dust mask for routine handling; powered air-purifying respirator (PAPR) for large spills.
 - Hand Protection: Replace gloves immediately if they are damaged or contaminated.

SECTION 9: Physical and Chemical Properties

- Physical State: Crystalline powder
- Color: White to creamy white
- Odor: Odorless
- Melting Point: 202-208°C
- Boiling Point: Not applicable (decomposes before boiling)
- Flammability: Combustible at high temperature (>300°C)
- Flash Point: >200°C (Closed Cup)



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- Autoignition Temperature: >350°C
- Solubility: Insoluble in water; soluble in chloroform, ethanol, DMSO; slightly soluble in ether
- Density (20°C): 1.13 g/cm³ (powder)
- Optical Rotation: +210° to +220° (c=1, chloroform, 25°C)
- Vapor Pressure (25°C): <0.001 hPa (negligible)
- Particle Size: 90% passing 100 mesh
- pH Value: Not applicable (insoluble in water)

SECTION 10: Stability and Reactivity

10.1 **Chemical Stability:** Stable under the recommended storage conditions (2-8°C, sealed, dark); decomposes at high temperature (>200°C) and strong light. 10.2 **Possibility of Hazardous Reactions:** No hazardous reactions under normal use and handling conditions. 10.3 **Conditions to Avoid:** High temperature, direct sunlight, moisture, contact with strong oxidizing agents, strong acids and strong bases. 10.4 **Incompatible Materials:** Hydrogen peroxide, potassium permanganate, concentrated sulfuric acid, concentrated sodium hydroxide. 10.5 **Hazardous Decomposition Products:** Carbon monoxide, carbon dioxide when burned; no toxic decomposition products under normal storage.

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

- Acute Toxicity: Oral (rat) LD₅₀ = 2200 mg/kg (harmful); Dermal (rabbit) LD₅₀ >5000 mg/kg (no acute dermal toxicity); Inhalation (rat) LC₅₀ >10 mg/m³ (4-hour exposure).
- Skin Corrosion/Irritation: No skin irritation (rabbit, 4-hour exposure test).
- Serious Eye Damage/Eye Irritation: No eye irritation (rabbit, 24-hour exposure test).
- Reproductive Toxicity: Category 1B; animal tests show it may affect fetal development and fertility.
- Target Organ Toxicity (Repeated Exposure): May cause liver function abnormalities and endocrine system disorder after prolonged exposure.
- Carcinogenicity: Not classified as a carcinogen by IARC, EPA or NTP.
- Mutagenicity: No mutagenic effects observed in standard in vitro and in vivo tests.

SECTION 12: Ecological Information

12.1 **Toxicity:** Harmful to aquatic organisms; Zebrafish LC₅₀ (96h) = 3.5 mg/L; Daphnia EC₅₀ (48h) = 2.8 mg/L. 12.2 **Persistence and Degradability:** Low biodegradability (BOD₅ /COD <0.2); persists in aquatic and soil environments for more than 6 months. 12.3 **Bioaccumulative Potential:** High bioaccumulation factor (BCF >1500) in aquatic organisms, accumulates in fatty tissues. 12.4 **Mobility in Soil:** Low mobility; binds strongly to soil organic matter. 12.5 **PBT and vPvB Assessment:** Classified as vPvB (very persistent, very bioaccumulative) under GHS criteria. 12.6 **Other Adverse Effects:** Disrupts the endocrine system of aquatic organisms, may cause reproductive dysfunction of fish and amphibians.

SECTION 13: Disposal Considerations



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13.1 Waste Treatment Methods

- Product Waste: Dispose of the unused product to a licensed hazardous waste treatment facility in accordance with local, national and international regulations.
- Packaging Waste: Rinse the empty packaging with a small amount of organic solvent, collect the rinse liquid as hazardous waste; dispose of the empty packaging as hazardous waste.
- Spillage Residue: Collect all contaminated materials as hazardous waste, do not mix with non-hazardous waste.

13.2 **Disposal Notes:** Incineration must be carried out in a hazardous waste incinerator with a gas treatment system; do not landfill the untreated waste.

SECTION 14: Transport Information

14.1 **UN Number:** UN 3077 (Environmentally hazardous substance, solid, n.o.s.)14.2 **UN Proper**

Shipping Name: Environmentally hazardous substance, solid, n.o.s. (Norethisterone)14.3

Transport Hazard Class: 9 (Miscellaneous dangerous goods)14.4 **Packaging Group:** III14.5

Environmental Hazards: Marine Pollutant (Yes); ADR/RID/IMDG/IATA: Class 9, environmentally hazardous.14.6 **Special Precautions for User**

- Transport the product in sealed original packaging, use refrigerated transport (2-8°C) for long-distance shipping.
- Avoid direct sunlight, high temperature, collision and rough handling during transport.
- Do not transport with food, beverages, aquatic products and non-hazardous goods.
- Accompany with complete transport documents indicating the UN number, hazard class and emergency contact.

14.7 **IATA Restrictions:** Permitted for air transport (cargo only), limited quantity per package (≤ 5 kg); no transport on passenger aircraft.

SECTION 15: Regulatory Information

15.1 National Regulations (China)

- Hazardous Chemical Safety Management Regulation: Classified as Class 9 hazardous chemical.
- Environmental Protection Law: Prohibited from discharge to water, soil and atmospheric environment.
- Pharmaceutical Administration Law: Regulated as a pharmaceutical raw material, subject to special production and use licensing.
- Occupational Disease Prevention and Control Law: Require workplace exposure monitoring and employee health checks.

15.2 International Regulations

- GHS Classification (Rev.9): Acute toxicity 4, Reproductive toxicity 1B, Target organ toxicity 2, Aquatic chronic 3.
- REACH (EU): Registered under REACH; listed in Annex XVII (reproductive toxicant restrictions).
- TSCA (US): Listed on the TSCA Inventory; subject to EPA hazardous waste regulations.



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- IMDG Code: Class 9, UN 3077, Marine Pollutant, Packaging Group III.

SECTION 16: Other Information

- This MSDS is prepared in accordance with GB/T 16483, GB/T 17519 and GHS Rev.9, based on current scientific and regulatory data.
- The supplier assumes no liability for any damage, injury or environmental pollution caused by improper use, storage, transport or disposal of this product.
- This document is intended for professional use by trained personnel only; not for general consumer distribution or use.
- This is the first revision of this MSDS, issued on 18 FEB 2026; it will be updated with the latest scientific and regulatory information.

