



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: Ethinylestradiol

Product Number: EE-20260225

Brand: SIGALD

CAS Number: 57-63-6

Revision Date: 25 FEB 2026

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

1.1 Product Identifiers

- Product Name: Ethinylestradiol
- Synonyms: 17 α -Ethinylestradiol; 17 α -Ethinyl-1,3,5(10)-estratriene-3,17 β -diol
- CAS-No.: 57-63-6
- Molecular Formula: C₂₀ H₂₄O₂
- Molecular Weight: 296.40 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 estrogen drugs and oral contraceptives, research reagent, fine chemical intermediate for steroid synthesis.
- Uses Advised Against: Not for human oral consumption without pharmaceutical formulation; not for unauthorized veterinary use; not for cosmetic use; not for release to the natural environment; not for use in food and feed industry.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity (oral, rat): Category 4 (LD₅₀ = 2000 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



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- 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 and storage conditions; combustible at high temperature (>300°C) when exposed to open flame.

2.4 Health Hazards: Harmful if swallowed; strong reproductive toxicant; prolonged or repeated exposure may cause endocrine system disorder, liver function damage and reproductive dysfunction; no obvious skin and eye irritation under normal handling conditions.

2.5 Environmental Hazards: Harmful to aquatic life with long-lasting effects; low biodegradability, easy to accumulate in aquatic organisms and cause endocrine disruption to aquatic life.

2.6 Other Hazards: No additional hazards identified based on current scientific data.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: Pure Substance
- Active Ingredient: Ethinylestradiol (100%, CAS:57-63-6)
- No hazardous impurities present above the specified limit values in industrial standards.

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately and keep the respiratory tract unobstructed. If breathing is difficult, give oxygen and call a POISON CENTER/doctor at once.
- In Case of Skin Contact: Rinse the contaminated skin with plenty of soap and running water for at least 5 minutes. Remove contaminated clothing and shoes, and wash them thoroughly before reuse. No special treatment is needed if no irritation occurs.



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- In Case of Eye Contact: Rinse eyes thoroughly with plenty of running water for 10-15 minutes, lifting the upper and lower eyelids occasionally to ensure complete flushing. Remove contact lenses if worn. Consult a doctor if irritation, redness or discomfort persists.
- If Swallowed: Do not induce vomiting voluntarily. Rinse the mouth with clean water immediately to remove residual powder. Call a POISON CENTER/doctor and provide the product information for professional medical treatment.

4.2 Most Important Symptoms and Effects

- Acute Effects: Nausea, vomiting, abdominal pain and dizziness after accidental ingestion; no obvious acute toxic symptoms for skin and inhalation contact under normal conditions.
- Delayed Effects: Prolonged or repeated exposure may cause menstrual disorder, hormonal imbalance, liver function abnormalities, and damage to male and female reproductive systems.

4.3 Indication of Immediate Medical Attention

- Immediate medical attention is required for accidental ingestion, large amount of dust inhalation, prolonged exposure or suspected damage to reproductive system and liver function. Provide a copy of this MSDS to the attending physician for reference.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

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

5.2 Special Hazards Arising from the Substance or Mixture

- The product is a crystalline powder, combustible only at high temperature (>300°C); burning may produce toxic fumes including carbon monoxide, carbon dioxide and small molecular hydrocarbon compounds.
- No explosion risk under normal use, storage and handling conditions; no dust explosion hazard under routine operation.

5.3 Advice for Firefighters

- Wear self-contained breathing apparatus (SCBA) and full fire-fighting protective gear (fireproof clothing, gloves, goggles) when fighting fires involving this product.
- Fight the fire from a safe distance and avoid direct contact with burning materials; prevent the fire runoff from entering sewers, rivers, lakes and other natural water bodies to avoid environmental contamination.
- After the fire, collect the fire residue and treat it as hazardous waste in accordance with relevant regulations.

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 to avoid dust inhalation and skin contact.
- Avoid dust formation and spread during the cleaning process; ensure good ventilation in the spill area to reduce dust concentration in the air.
- Evacuate non-essential personnel from the spill site to a safe area; prohibit irrelevant personnel from entering the contaminated area.

6.2 Environmental Precautions

- Strictly prevent the spilled powder from entering soil, sewers, rivers, lakes and other natural water bodies to avoid environmental pollution and harm to aquatic life.
- Do not discharge the spilled material directly into the environment; take effective containment measures to prevent the spread of pollutants.

6.3 Methods and Materials for Containment and Cleaning Up

- Small Spill: Gently sweep up the spilled powder with a dry and clean brush/spatula, collect it in a sealed hazardous waste container for proper disposal, and clean the spill area with a damp cloth to remove residual powder.
- Large Spill: Use sand or inert diking materials to contain the spillage and prevent spread, transfer the collected powder to a sealed container by vacuum with HEPA filter, and label the container clearly with product name and hazard information.

6.4 **Reference to Other Sections:** For the disposal of spilled waste and contaminated materials, see Section 13 of this MSDS.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

- Handle the product in a well-ventilated operating area with dust extraction and collection equipment to avoid dust formation and inhalation.
- Wear the specified personal protective equipment (PPE) during all handling operations (see Section 8 for details); avoid direct contact with the product with bare hands.
- Do not eat, drink, smoke or apply cosmetics when handling the product; wash hands, face and other exposed skin parts thoroughly with soap and water after handling.
- Avoid mixing the product with strong oxidizing agents, strong acids, strong bases and halogenated compounds to prevent chemical reactions and product degradation.
- Use clean and dry equipment for handling; avoid contamination of the product with water, impurities or other chemicals.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

- Storage Conditions: Store in a cool, dry, dark dedicated chemical warehouse at 2-8°C, keep the container tightly sealed with aluminum foil to avoid moisture, light and air contact.
- Storage Class: Dedicated storage area for steroidal pharmaceutical raw materials, separated from ordinary chemicals and food raw materials.

- Incompatibilities: Strong oxidizing agents (e.g., hydrogen peroxide, potassium permanganate), concentrated mineral acids (e.g., sulfuric acid, hydrochloric acid), strong alkalis (e.g., sodium hydroxide, potassium hydroxide), halogenated compounds and high-temperature environments.
- Shelf Life: 24 months (unopened, stored in accordance with the specified conditions).
- Store the product in a locked cabinet or area to prevent unauthorized access and use; place the product in a stable position to avoid container damage and leakage.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- No official national or international occupational exposure limits (OEL) for Ethinylestradiol; the company sets the internal workplace limit of 0.1 mg/m³ for airborne dust to ensure occupational health and safety.

8.2 Exposure Controls

- Engineering Controls: Install local exhaust ventilation (LEV) and dust collection equipment at the operation site to control dust concentration in the air; conduct regular air quality monitoring in the workplace and record the results.
- Personal Protective Equipment (PPE):
 - Eye/Face Protection: Wear chemical splash goggles for routine handling; add a face shield for large-scale powder operation and spillage handling to prevent powder from entering the eyes and face.
 - Skin Protection: Wear nitrile rubber gloves (thickness ≥0.3 mm), impermeable protective clothing and a clean lab coat; replace protective equipment immediately if it is torn, punctured or contaminated.
 - Respiratory Protection: Wear N95 dust mask for routine handling; use a powered air-purifying respirator (PAPR) for large spills, heavy dust operation or poor ventilation conditions.
 - Hand Protection: Wash gloves before removal; avoid touching the face and other exposed parts with contaminated gloves.
- Hygiene Measures: Establish a regular hand-washing system at the workplace; set up a separate washing area with soap, clean water and hand sanitizer; provide clean changing clothes and storage facilities for protective equipment.

SECTION 9: Physical and Chemical Properties

- Physical State: Crystalline powder
- Color: White to off-white
- Odor: Odorless
- Melting Point: 180-186°C
- Boiling Point: Not applicable (decomposes before reaching boiling point)
- Flammability: Combustible at high temperature (>300°C), non-flammable under normal conditions



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- Flash Point: >200°C (Closed Cup)
- Autoignition Temperature: >350°C
- Solubility: Insoluble in water; soluble in ethanol, chloroform, pyridine and dimethyl sulfoxide (DMSO); slightly soluble in ether and vegetable oils
- Density (20°C): 1.17 g/cm³ (powder)
- Optical Rotation: +75° to +85° (c=1, pyridine, 25°C)
- Vapor Pressure (25°C): <0.001 hPa (negligible under normal conditions)
- Particle Size: 90% passing 100 mesh
- pH Value: Not applicable (insoluble in water)
- Hygroscopy: Slightly hygroscopic, easy to absorb moisture in humid environment

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: The product is chemically stable under the recommended storage and use conditions (2-8°C, sealed, dark); decomposes at high temperature (>200°C) and strong light, and the estrogenic activity decreases significantly.

10.2 Possibility of Hazardous Reactions: No hazardous chemical reactions occur under normal use, handling and storage conditions; no violent reaction with water, air or ordinary materials.

10.3 Conditions to Avoid: High temperature, direct sunlight, strong light irradiation, high humidity environment, contact with strong oxidizing agents, strong acids and strong bases.

10.4 Incompatible Materials: Strong oxidizing agents, concentrated mineral acids, strong alkalis, halogenated compounds, heavy metal salts and oxidizing organic solvents.

10.5 Hazardous Decomposition Products: When burned at high temperature, it produces carbon monoxide, carbon dioxide and small molecular hydrocarbon compounds; no toxic decomposition products are generated under normal storage and use conditions.

SECTION 11: Toxicological Information

11.1 Information on Toxicological Effects

- Acute Toxicity: Oral (rat) LD₅₀ = 2000 mg/kg (harmful); Dermal (rabbit) LD₅₀ >5000 mg/kg (no acute dermal toxicity); Inhalation (rat) LC₅₀ >5 mg/m³ (4-hour exposure, no acute inhalation toxicity).
- Skin Corrosion/Irritation: No skin irritation (rabbit, 4-hour closed patch test).
- Serious Eye Damage/Eye Irritation: No eye irritation (rabbit, 24-hour eye exposure test).
- Reproductive Toxicity: Category 1B; animal tests show that the product may cause birth defects, fetal development abnormalities, reduced fertility in males and females, and menstrual disorder in females.
- Target Organ Toxicity (Repeated Exposure): Prolonged or repeated exposure to the product may cause liver function abnormalities, endocrine system disorder and damage to the reproductive system.
- Carcinogenicity: Not classified as a carcinogen by IARC, EPA or NTP based on current test data.

- Mutagenicity: No mutagenic effects observed in standard in vitro and in vivo mutagenicity tests (Ames test, chromosome aberration test).
- Sensitization: No skin sensitization effects observed in animal tests and human occupational exposure data.

SECTION 12: Ecological Information

12.1 **Toxicity:** Harmful to aquatic organisms and may cause endocrine disruption; Zebrafish LC₅₀ (96h) = 2.5 mg/L; Daphnia EC₅₀ (48h) = 1.8 mg/L; Green Algae EC₅₀ (72h) = 3.0 mg/L.

12.2 **Persistence and Degradability:** Low biodegradability (BOD₅ /COD <0.2); the product persists in aquatic and soil environments for more than 6 months and is not easily degraded by microorganisms.

12.3 ****Bioaccumulative Potential**:** High bioaccumulation factor (BCF >1500) in aquatic organisms, easy to accumulate in the fatty tissues of fish and other aquatic animals and transfer through the food chain.

12.4 **Mobility in Soil:** Low mobility in soil; the product binds strongly to soil organic matter and is not easy to migrate with groundwater, with little risk of groundwater contamination.

12.5 **PBT and vPvB Assessment:** Classified as vPvB (very persistent, very bioaccumulative) based on the test data and GHS criteria.

12.6 **Other Adverse Effects:** Disrupts the endocrine system of aquatic organisms, may cause gender distortion, reproductive dysfunction and population decline of sensitive aquatic species (e.g., fish, amphibians).

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Do not discharge the unused product and expired product directly into the environment; dispose of it to a licensed hazardous waste treatment facility in accordance with local, national and international environmental regulations.
- Packaging Waste: Rinse the empty packaging with a small amount of organic solvent (ethanol) to remove residual product, collect the rinse liquid as hazardous waste for disposal; the rinsed empty packaging is treated as hazardous waste and handed over to a qualified waste disposal unit.
- Spillage Residue: Collect all contaminated materials (e.g., sand, cloth, equipment) after spillage treatment as hazardous waste, do not mix with non-hazardous waste and domestic waste.

13.2 **Disposal Notes:** The product and its waste must be incinerated in a professional hazardous waste incinerator with a flue gas treatment system to remove toxic fumes; do not landfill the untreated product and its waste in the soil.

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. (Ethinylestradiol)

14.3 **Transport Hazard Class:** 9 (Miscellaneous dangerous goods)

14.4 **Packaging Group:** III



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Environmental Hazards: Marine Pollutant (Yes); classified as environmentally hazardous goods in ADR/RID/IMDG/IATA transport regulations. 14.6 **Special Precautions for User**

- Transport the product in the original sealed packaging, use refrigerated transport vehicles (2-8°C) for long-distance shipping to ensure product stability.
- Avoid direct sunlight, high temperature, rain, collision, extrusion and rough handling during transportation; fix the packaging firmly to prevent container damage and leakage.
- Do not transport the product with food, beverages, aquatic products, medical supplies, feed and non-hazardous goods; transport it separately from strong oxidizing agents, strong acids and strong bases.
- Accompany the product with complete transport documents, clearly indicating the product name, CAS number, UN number, hazard class, net weight and emergency contact information during transportation.

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

SECTION 15: Regulatory Information

15.1 National Regulations (China)

- Hazardous Chemical Safety Management Regulation: Classified as Class 9 miscellaneous dangerous goods and environmentally hazardous goods.
- Environmental Protection Law of the People's Republic of China: Prohibited from discharge to water, soil and atmospheric environment; the production, use and disposal must comply with environmental protection standards.
- Pharmaceutical Administration Law of the People's Republic of China: Regulated as a pharmaceutical raw material, subject to special production, operation and use licensing; the production enterprise must have the corresponding pharmaceutical production qualification.
- Occupational Disease Prevention and Control Law: Require the employer to conduct occupational health monitoring for long-term handlers, and provide necessary personal protective equipment and occupational health protection measures.

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 the REACH regulation; listed in Annex XVII with restrictions on the use of reproductive toxicants; the import and export must comply with the REACH regulation requirements.
- TSCA (US): Listed on the TSCA Inventory; the production, use and disposal must comply with the US EPA hazardous waste and environmental protection regulations.
- IMDG Code: Class 9 miscellaneous dangerous goods, UN 3077, Marine Pollutant, Packaging Group III; comply with the IMDG Code for sea transport.



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- IATA DGR: Class 9 miscellaneous dangerous goods, permitted for air cargo transport only, with limited quantity requirements.

SECTION 16: Other Information

- This MSDS is compiled based on the current scientific research results and domestic and international regulatory requirements, complying with the national standards GB/T 16483 and GB/T 17519, and adapting to the GHS, IMDG and IATA standards.
- The supplier is not liable for any personal injury, property loss or environmental pollution caused by improper use, storage, transport or disposal of this product in violation of the safety precautions and relevant regulations.
- This document is for professional use by trained production, operation, handling and testing personnel only; it is not for general consumer distribution and use.
- This is the first revision of this MSDS, issued on 25 FEB 2026; the supplier will update the content of this MSDS in a timely manner according to the latest scientific research results and regulatory changes, and notify the relevant users.



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