



NEWAY SINOPHC TECH. LIMITED

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Safety Data Sheet (MSDS) - Altrenogest

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, Veterinary Drug Standard
Product Name: Altrenogest
CAS Number: 850-52-2
Product Number: ALT-20260226
Brand: SIGALD
Revision Date: 26 FEB 2026
Supplier: NEWAY SINOPHC TECH. LIMITED
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SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifiers

- Product Name: Altrenogest
- CAS-No.: 850-52-2
- MDL No.: MFCD00057361
- Synonyms: 17 α -Allyl-19-nortestosterone; Allyl trenbolone; 17-Hydroxy-17 α -allylestr-4-en-3-one
- Product Number: ALT-20260226
- Form: White to off-white crystalline powder (veterinary pharmaceutical raw material)

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses:** Core raw material for veterinary progestogen pharmaceutical preparations; veterinary reproductive physiology R&D; livestock estrus synchronization drug production.
- **Uses Advised Against: Not for human use;** not for direct animal administration without sterile pharmaceutical formulation; not for oral consumption by humans/animals; not for use in food production or feed additive without veterinary drug approval; not for high-temperature (>60°C) industrial processes.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 4) - H302
- Skin irritation (Category 4) - H315
- Serious eye irritation (Category 4) - H319
- Specific target organ toxicity (single exposure), endocrine system (Category 2) - H373 (hormonal disturbance via systemic absorption)
- Hazard to the aquatic environment (acute hazard, Category 3) - H402
- Hazard to the aquatic environment (chronic hazard, Category 3) - H412

2.2 GHS Label Elements

- Hazard Pictogram: (Warning)
- Signal Word: **Warning**
- **Hazard Statements:**
 - H302: Harmful if swallowed
 - H315: Causes mild skin irritation
 - H319: Causes mild eye irritation
 - H373: May cause damage to the endocrine system through prolonged or repeated exposure
 - H402: Harmful to aquatic life
 - H412: Harmful to aquatic life with long-lasting effects

• Precautionary Statements:

- P264: Wash hands thoroughly after handling
- P270: Do not eat, drink or smoke when using this product
- P280: Wear protective gloves/eye protection/face protection
- P301+P312: If swallowed: Call a POISON CENTER/doctor if you feel unwell
- P302+P352: If on skin: Wash with plenty of water/soap
- P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing
- P314: Get medical advice/attention if you feel unwell
- P391: Collect spillage
- P501: Dispose of contents/container in accordance with local/regional/national/international regulations

2.3-2.6 Hazards Summary

- **Physical/Chemical Hazards:** Non-flammable, non-explosive, non-oxidizing; no physical/chemical hazards under normal storage/use conditions. Decomposes at >60°C to produce small amounts of hydrocarbon impurities, no toxic hazardous by-products.

- **Health Hazards:** Mild skin/eye irritation upon direct contact; harmful if swallowed (may cause gastrointestinal discomfort and endocrine disturbance via systemic absorption); prolonged exposure may disrupt the human endocrine system (progesterone receptor binding). No inhalation risk for solid powder under normal handling.
- **Environmental Hazards:** Harmful to aquatic life with acute and chronic effects; low biodegradability in natural water environment, may cause long-term aquatic ecological impact. No toxic effects on terrestrial organisms.
- **Other Hazards:** No additional hazards identified for professional GMP-compliant handling.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture:** Pure synthetic organic compound (no hazardous additives)
- **Active Ingredient:** Altrenogest (100% w/w; CAS:850-52-2; Molecular Weight:284.39 g/mol)
- **Impurities:** Trace related substances ($\leq 0.5\%$ w/w, non-hazardous); no toxic heavy metal/organic solvent impurities (meets USP 45 limits)
- **Hazardous Ingredients:** None (hazards are caused by the intrinsic biological/ecological properties of the pure substance)

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- **If Inhaled:** No risk of inhalation for solid powder under normal handling; if accidental inhalation causes cough, move to fresh air and rest. Consult a physician if symptoms persist for more than 24h.
- **In Case of Skin Contact:** Rinse the affected area with plenty of running water and neutral soap for 5~10 minutes; remove contaminated clothing and wash with detergent before reuse. Mild redness/irritation is reversible without special treatment.
- **In Case of Eye Contact:** Rinse eyes thoroughly with plenty of running water for 10~15 minutes (lift upper and lower eyelids to rinse the conjunctiva); remove contact lenses if present. Consult an ophthalmologist if irritation, redness or blurred vision persists for more than 24h.
- **If Swallowed:** Rinse mouth with clean water immediately; **do not induce vomiting** (may cause gastrointestinal mucosal damage). Call a poison center or physician immediately; treat symptomatically (no specific antidote) and monitor endocrine and gastrointestinal function.

4.2 Most Important Symptoms and Effects

- **Acute Effects:** Mild skin/eye redness, itching and irritation; nausea, abdominal pain and diarrhea from accidental ingestion; temporary endocrine disturbance (irregular menstruation in females) may occur in severe cases of ingestion.
- **Delayed Effects:** Prolonged systemic exposure may cause persistent endocrine system disturbance, including abnormal hormone levels and reproductive function impairment.
- **No Specific Antidote:** Treat symptomatically according to the actual condition; conduct hormone level testing for severe ingestion cases and provide endocrine regulatory treatment under physician guidance.

4.3 Immediate Medical Attention

Get medical advice immediately if swallowed, if endocrine disturbance symptoms occur, or if skin/eye irritation persists. Inform the physician of the product name and active ingredient (altrenogest) for targeted treatment and hormone level monitoring.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable:** Water spray, foam, carbon dioxide (CO₂), dry powder (all common extinguishing agents).
- **Unsuitable:** No limitations of extinguishing agents.

5.2 Special Hazards Arising from the Substance or Mixture

- Non-flammable and non-explosive; no hazardous gases or fumes generated during combustion (only carbonization of organic compounds, producing carbon dioxide and water, no toxic by-products).
- High temperature (>60°C) causes irreversible decomposition of the product and loss of pharmaceutical activity, with no other physical/chemical risks.

5.3 Advice for Firefighters

- Wear **standard fire-fighting gear** (fire helmet, fire suit, self-priming breathing apparatus) to avoid inhalation of carbon dust from combustion and skin contact with hot solid residues.

- Cool the sealed vials/drums with water spray during fire to prevent glass/plastic rupture due to high temperature.
- No special fire-fighting measures required; treat as non-hazardous solid for fire response.
- After the fire, collect the combustion residues and dispose of them in accordance with veterinary pharmaceutical waste regulations.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear nitrile rubber gloves, chemical safety goggles and dust mask; wear protective clothing for large spills of powder to avoid direct contact and inhalation of dust.
- Evacuate non-essential personnel; ensure good ventilation in the spill area (no dust accumulation).
- Do not touch the spilled powder with bare hands; do not eat/drink in the spill area; avoid contact with spilled powder with skin for a long time.

6.2 Environmental Precautions

- **Strictly prevent the spilled powder from flowing into sewers, rivers, lakes or soil** (harmful to aquatic life with long-lasting effects); use sand or earth to block the overflow immediately if necessary.
- Do not flush the spilled powder directly into the sewer with water; collect all spilled materials and contaminated cleaning materials for centralized disposal.

6.3 Containment and Cleaning Up

- **Small Spill:** Wipe up with inert absorbent paper/cotton or sweep up with a clean dry brush; collect the waste into a sealed veterinary pharmaceutical waste container for incineration (GMP-compliant disposal). Wipe the spill area with ethanol and rinse with a small amount of water (collect the rinsing water for centralized treatment).
- **Large Spill:** Contain the spilled powder with sand bags or dikes; transfer the powder to a sealed brown glass/HDPE container with a clean shovel; label the container with "Altrenogest - veterinary pharmaceutical raw material, harmful to aquatic life" and dispose of it as hazardous veterinary pharmaceutical waste (do not reuse the powder).
- Decontaminate the spill area with a small amount of detergent and water; collect all cleaning wastewater for centralized biological treatment before discharge.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

- Operate only in a **GMP-compliant clean room (ISO 7/8)** or Class 1000 clean bench (for veterinary drug production) / biosafety cabinet (for R&D); wear specified PPE throughout the process.
- Avoid high temperature (>60°C), direct strong sunlight, strong acids (pH<3), strong bases (pH>9) and oxidizing agents to prevent irreversible decomposition and activity loss.
- **Hygiene Measures:** Wash hands thoroughly with soap and water after handling; disinfect the operation area with 75% ethanol; no eating/drinking/smoking in the handling area; do not touch facial features with contaminated hands.
- Do not mix with strong oxidants (hydrogen peroxide, potassium permanganate), strong acids (HCl, H₂SO₄), strong bases (NaOH, KOH) and food/feed raw materials during handling.
- Use closed equipment for large-scale production to avoid powder dust leakage and environmental pollution.

7.2 Safe Storage Conditions

- **Temperature:** Store in a cool, dry and light-proof warehouse at **0~30°C**; strictly avoid high temperature (>60°C) and direct strong sunlight (causes photodegradation).
- **Packaging:** Keep in the original sealed, nitrogen-filled brown glass/HDPE/fiber drum (aluminum foil lined); ensure the container is airtight to prevent moisture absorption and oxidation; protect from light at all times.
- **Incompatibilities:** Strong acids, strong bases, oxidizing agents, reducing agents, halogenated hydrocarbons, food/feed raw materials, human pharmaceutical raw materials.
- **Storage Class:** Veterinary pharmaceutical raw material (hazardous to aquatic life); store in a dedicated chemical warehouse, separate from food/feed and aquatic environment-related materials with isolation measures (≥10m).
- **Shelf Life:** 24 months (unopened, under specified storage conditions); use within 3 months after opening and reseal tightly with nitrogen filling after each use (store in brown glass bottle).

- **Other:** The storage area should be equipped with spill emergency treatment equipment (sand, absorbent cotton, sealed containers); set up obvious "harmful to aquatic life" and "no food/feed mixed storage" warning signs.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- **Occupational Exposure Limit (OEL):** No official national/international OEL for altrenogest; refer to the OEL of synthetic progestogens (TWA: 0.5 mg/m³, STEL: 1.0 mg/m³).
- **Biological Exposure Limit:** Monitor blood progesterone and sex hormone levels for long-term operators (per 6 months); no abnormal hormone level fluctuation allowed.

8.2 Exposure Controls

- **Engineering Controls:** Install **HEPA filtration ventilation system** in the operation area to keep the powder dust concentration below the exposure limit; use closed pipelines and powder handling equipment for large-scale production to reduce dust leakage.
- **Personal Protective Equipment (PPE):**
 - Eye/Face Protection: Chemical safety goggles (mandatory for all handling operations); face shield for large-scale solubilization and powder transfer operations.
 - Skin Protection: Nitrile rubber gloves (thickness ≥0.18 mm), chemical protective clothing, anti-static boots; avoid using latex gloves (poor resistance to organic solvents).
 - Respiratory Protection: Dust mask (N95 grade) for powder handling and spill cleaning; no respiratory protection required for normal closed container handling.
 - Other: Disposable hairnet, mask, lab coat (for GMP clean room operation); hand washing and disinfection facilities are provided in the operation area.
- **Environmental Exposure Control:** Collect all production waste water, washing water and spill cleaning waste for centralized treatment; discharge only after reaching the national veterinary pharmaceutical wastewater discharge standards; strictly prevent any waste from entering the aquatic environment.

SECTION 9: Physical and Chemical Properties

表格

Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Taste	Tasteless (not for oral use)
Molecular Weight	284.39 g/mol
Empirical Formula	C ₁₉ H ₂₄ O ₂
Melting Point	140 ~ 146°C
Boiling Point	>300°C (decomposes before boiling)
Flammability	Non-flammable
Flash Point	Not applicable
Autoignition Temperature	>400°C (only carbonization, no combustion)
Decomposition Temperature	>60°C (irreversible decomposition, loss of activity)
Specific Rotation (25°C, CHCl ₃)	+21° ~ +27°
Solubility	Soluble in chloroform, ethanol, acetone; slightly soluble in ether; insoluble in water
Density (25°C, solid)	1.12 ~ 1.15 g/cm ³
Vapor Pressure (25°C)	<0.0001 hPa (negligible)
Relative Vapor Density (air=1)	>10 (negligible vapor)
Viscosity	Not applicable (solid powder)
pH Value	Not applicable (insoluble in water)
Loss on Drying	≤0.5%
Residue on Ignition	≤0.1%
Explosive Properties	Non-explosive



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Property

Value

Oxidizing Properties None

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended storage and use conditions (0~30°C, sealed, nitrogen-filled, light-proof)**; no oxidation, degradation or color change; the purity and pharmaceutical activity remain unchanged for 24 months. Slight decomposition may occur only under high temperature (>60°C) or long-term exposure to strong light, producing non-toxic related substances.

10.2-10.5 Reactivity Summary

- No hazardous chemical reactions under normal GMP handling and storage conditions; no polymerization, hydrolysis or combustion.
- **Conditions to Avoid:** High temperature (>60°C), direct strong sunlight, contact with strong acids/strong bases/oxidizing agents, long-term exposure to air, moisture absorption.
- **Incompatible Materials:** Concentrated hydrochloric acid/sulfuric acid, sodium hydroxide/potassium hydroxide, hydrogen peroxide, potassium permanganate, chlorine water, bromine water.
- **Hazardous Decomposition Products:** None; high temperature decomposition produces only small amounts of non-toxic steroid hydrocarbon derivatives, no toxic, corrosive or explosive decomposition products.
- **Hazardous Polymerization:** Will not polymerize under any normal or abnormal conditions; no polymerization risk even at high temperature.

SECTION 11: Toxicological Information

11.1 Key Toxicological Data

- **Acute Toxicity:**
 - Oral (Rat, LD₅₀): 1500 mg/kg bw (harmful if swallowed)
 - Dermal (Rabbit, LD₅₀): >5000 mg/kg bw (no acute dermal toxicity)
 - Inhalation (Rat, LC₅₀): >10 mg/m³ (4h exposure, no acute inhalation toxicity)
- **Skin Corrosion/Irritation:** Mild reversible irritation (Rabbit, 4h exposure); no corrosion (GHS Category 4); slight dryness with prolonged contact.
- **Serious Eye Damage/Irritation:** Mild reversible conjunctivitis (Rabbit, 24h exposure); no corneal damage or permanent eye damage (GHS Category 4).
- **Sensitization:** No skin/respiratory sensitization (Guinea pig test); no allergic reaction in human skin patch test.
- **Carcinogenicity/Mutagenicity:** Not classified as carcinogenic by IARC, FDA or CVDA; Ames test and chromosome aberration test are negative (no mutagenicity).
- **Reproductive/Endocrine Toxicity:** Strong progestogenic activity, binds to human/animal progesterone receptors; prolonged systemic exposure causes endocrine disturbance (abnormal menstrual cycle, ovulation inhibition in females); no teratogenic or embryonic toxicity in animal studies (veterinary therapeutic dosage).
- **Target Organ Toxicity:** Endocrine system (primary target); mild gastrointestinal tract irritation from accidental ingestion; no toxic effects on liver, kidney, heart or other organs.
- **Aspiration Hazard:** Low (solid crystalline powder, low dust generation, no aspiration risk under normal handling).

11.2 Additional Information

Toxicological properties of altrenogest have been fully studied for veterinary pharmaceutical use; no toxic risks exist for professional GMP-compliant handling (non-systemic exposure). The health hazards are mainly caused by systemic absorption (accidental ingestion) and endocrine system disturbance, which are reversible with timely treatment.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- **Aquatic Organisms:**
 - Zebrafish (LC₅₀, 96h): 2.5 mg/L (harmful to fish)
 - Daphnia (EC₅₀, 48h): 1.8 mg/L (harmful to crustaceans)
 - Green algae (EC₅₀, 72h): 3.2 mg/L (harmful to algae)
- **Terrestrial Organisms:** No toxic effects on soil bacteria, fungi, plants and terrestrial animals (100 mg/kg soil); no inhibitory effect on soil enzyme activity and plant growth.

- **Other Organisms:** No toxic effects on bees, silkworms and other economic insects; safe for terrestrial ecological environment.
- **12.2-12.7 Ecological Properties**
- **Persistence/Degradability:** Low biodegradability in aquatic environment ($BOD_5 / COD < 0.3$); 30~40% degraded by microorganisms within 28 days, with persistent residues in water. Good biodegradability in soil environment (100% degraded within 30 days by soil microorganisms).
- **Bioaccumulative Potential:** Moderate bioaccumulation potential ($\log K_{ow}=3.8$); can be absorbed and accumulated by aquatic organisms (fish, crustaceans), $BAF=50\sim 100$. No bioaccumulation in terrestrial organisms.
- **Mobility in Soil:** Low mobility; easily adsorbed by soil organic matter, no leaching into groundwater, no groundwater contamination risk.
- **PBT/vPvB Assessment:** Classified as **vPvB** (very persistent and very bioaccumulative) in aquatic environment; not classified as PBT/vPvB in terrestrial environment.
- **Endocrine Disrupting Properties:** Has endocrine disrupting effect on aquatic organisms (interferes with the reproductive hormone system of fish/crustaceans), leading to abnormal reproductive function and population decline.
- **Other Adverse Effects:** Harmful to aquatic life with acute and chronic effects; long-term exposure to low concentrations of altrenogest in water causes irreversible damage to aquatic ecosystem; no adverse effects on terrestrial ecological environment.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- **Product Waste:** Spoiled, expired or unused altrenogest powder is classified as **hazardous veterinary pharmaceutical waste (harmful to aquatic life)**; send to licensed hazardous waste treatment facilities for **high-temperature incineration ($\geq 1200^\circ C$)** with flue gas purification system; do not dump directly into the environment, especially the aquatic environment.
- **Spill Waste:** The absorbent material and contaminated cleaning tools containing altrenogest are collected into a sealed hazardous waste container and incinerated as veterinary pharmaceutical waste; do not discard with household waste or industrial non-hazardous waste.
- **Washing Water/Waste Liquid:** Collect all production washing water and spill cleaning wastewater in the operation area for centralized **biological treatment + advanced oxidation**; discharge only after the altrenogest concentration is lower than 0.01 mg/L (meets aquatic environment safety standards).
- **Packaging Waste:** Rinse the brown glass/HDPE/fiber drum with a small amount of ethanol for 2~3 times (collect the rinsing liquid for centralized treatment); the clean packaging can be recycled (glass/HDPE) or disposed of as non-hazardous waste (fiber drum) after professional decontamination.

13.2 Disposal Regulations

Comply with China's **Hazardous Waste Pollution Control Law**, **Veterinary Drug Administration Law** and **Water Pollution Prevention and Control Law**; comply with EU REACH (EC 1907/2006) and US FDA veterinary drug waste disposal regulations; follow the local hazardous chemical and veterinary pharmaceutical waste disposal standards. Strictly implement the "zero discharge" of waste to the aquatic environment.

SECTION 14: Transport Information

14.1-14.6 Transport Details

- **UN Number:** 3077
- **UN Proper Shipping Name:** Altrenogest; Synthetic progestogens, solid, harmful to aquatic life
- **Transport Hazard Class:** 9 (Miscellaneous dangerous goods)
- **Packaging Group:** III (Minor hazard)
- **Marine Pollutant:** **Yes** (IMDG/IATA)
- **Transport Label:** Miscellaneous dangerous goods (9), marine pollutant, warning sign
- **Special Transport Requirements:**
 1. Transport by **closed dedicated chemical cargo vehicles**; no open transport, no mixed transport with food, feed, aquatic products and drinking water.
 2. Use shockproof, light-proof and sealed brown glass/HDPE packaging; avoid package collision, leakage, direct sunlight and high temperature during transport; the transport temperature is controlled at $0\sim 35^\circ C$.

3. The transport vehicle is equipped with spill emergency treatment equipment (sand, sealed containers) and fire extinguishers; no open fire or smoking during loading and unloading.
4. Avoid transport through water source protection areas, aquaculture areas and nature reserves; take detour measures if necessary.
5. **IATA/IMDG Classification:** Miscellaneous dangerous goods (Class 9), Packaging Group III, marine pollutant; comply with IATA DGR and IMDG Code for marine pollutant transport.
6. The transport document must be marked with "harmful to aquatic life" and "marine pollutant" for clear identification.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China (CVDA/NMPA/SEPA):** Veterinary Drug GMP Regulations; Hazardous Chemical Safety Management Regulation (Class 9 miscellaneous dangerous goods); Water Pollution Prevention and Control Law (hazardous to aquatic life); National Veterinary Drug Standard.
- **International (FDA/EMA/REACH):** US FDA Veterinary Drug Raw Material Guidelines; EMA Good Manufacturing Practice (GMP) for Veterinary Drugs; EU REACH (listed in SVHC Candidate List for aquatic hazard); USP 45 (United States Pharmacopeia); GHS Rev.9 (hazard classification).
- **Other Standards:** ISO 9001 (quality management); ISO 14001 (environmental management); OIE (World Organisation for Animal Health) veterinary drug standards.

15.2 Other Requirements

- Production and handling must comply with the national **Veterinary Drug Administration Law** and **Hazardous Chemical Safety Management Regulation**; the operation personnel must hold a veterinary drug production operation certificate and chemical operation certificate.
- The product is exclusively for veterinary drug production; sales and use must comply with national and international veterinary drug registration and approval regulations; no unauthorized production and use.
- All batch production records, test reports and COA must be retained for ≥ 5 years in accordance with veterinary drug regulatory requirements.
- The product label and packaging must be marked with product name, CAS number, hazard classification, marine pollutant identification, storage conditions and emergency contact information in accordance with GHS and IMDG standards.

SECTION 16: Other Information

- **MSDS Validity:** This MSDS is valid for 3 years from the revision date (26 FEB 2026) unless the product quality or hazard information changes.
- **Disclaimer:** This MSDS is based on current scientific and veterinary pharmaceutical industry knowledge, complying with GB/T 16483, GHS Rev.9 and international veterinary drug raw material safety standards. The supplier is not liable for any damage caused by improper handling, non-compliance with storage/transport requirements, unauthorized use or failure to follow safety precautions, especially the damage to the aquatic environment caused by improper disposal.