



NEWAY SINOPHC TECH. LIMITED

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Technical Data Sheet (TDS)

1. Product Overview

Product Name: Megestrol **English Name:** Megestrol **CAS Number:** 595-33-5 **Molecular Formula:** $C_{24}H_{32}O_4$ **Molecular Weight:** 384.51 g/mol **Product Characteristics:** Synthetic progestational steroid hormone, a derivative of progesterone with high progestational activity and weak androgenic activity. White to off-white crystalline powder, odorless, insoluble in water, soluble in chloroform and ethanol, slightly soluble in ether. Stable under recommended storage conditions, exhibits strong progestational, antiestrogenic and antiovaratory effects, with high purity and stable biological activity, serving as a core raw material for progestogen pharmaceutical formulations.

2. Technical Specifications (Complies with Industrial Standards)

Appearance: White to off-white crystalline powder **Assay (HPLC):** $\geq 98.5\%$ **Melting Point:** 213-219°C **Loss on Drying:** $\leq 0.5\%$ **Residue on Ignition:** $\leq 0.1\%$ **Heavy Metals (Pb):** ≤ 10 ppm **Heavy Metals (As):** ≤ 2 ppm **Related Substances (Total):** $\leq 1.0\%$ **Optical Rotation (c=1, chloroform, 25°C):** +158° to +166° **Solubility:** Insoluble in water, soluble in chloroform/ethanol, slightly soluble in ether **Storage Stability:** Stable for 24 months at 2-8°C (sealed, dark condition) **pH Value:** Not applicable (insoluble in water)

3. Product Advantages

High Purity: Assay $\geq 98.5\%$, low impurity content, consistent batch-to-batch quality meeting pharmaceutical raw material standards.

Strong Progestational Activity: High biological potency with obvious antiovaratory and endometrial transformation effects, suitable for various progestogen drug development.

Excellent Stability: No easy degradation under recommended storage conditions, long shelf life and stable biological activity.

Good Solubility: Soluble in common organic solvents, easy for the development of oral, injectable and other pharmaceutical formulations.

Standardized Production: Manufactured in accordance with ISO 9001 quality management system, with complete and reliable testing data and strict quality control.

4. Application Fields

- **Pharmaceutical Industry:** Raw material for human pharmaceutical formulations (for the treatment of menstrual disorders, endometriosis, luteal phase insufficiency, and as a component of contraceptives).
- **Research & Development:** Laboratory research on progesterone hormone mechanism, reproductive system drug development and steroid hormone activity testing.
- **Fine Chemicals:** Intermediate for the synthesis of other progestogen derivatives and modified steroid hormone products.

5. Usage Methods

- **Pharmaceutical Formulation:** Dissolve in appropriate organic solvent (chloroform/ethanol) according to formulation requirements, prepare oral tablets, capsules or injectable formulations; adjust the concentration and dosage based on specific drug specifications and clinical needs.
- **Research Use:** Prepare standard solutions with chloroform (1-5 mg/mL) for laboratory tests and scientific research, the specific dosage is determined by the research protocol.

- Note: Strictly follow national pharmaceutical regulations and industrial standards for use, only for industrial production and scientific research purposes, not for unauthorized use.

6. Packaging & Storage

Packaging Specifications:

- 100 g/bottle (HDPE bottle with aluminum foil seal)
- 500 g/bottle (HDPE bottle with aluminum foil seal)
- 1 kg/tin can (sealed tin can with inner plastic bag)
- 5 kg/fiber drum (sealed fiber drum with inner plastic bag)
- Custom packaging available upon request.

Storage Conditions:

- Store in a cool, dry, dark place at 2-8°C, keep the container tightly sealed to avoid moisture and light.
- Keep away from heat, open flame, strong oxidizing agents, strong acids and strong bases.
- Store separately from food, beverages, aquatic products and raw materials for edible use.**Shelf Life:** 24 months (unopened, under specified storage conditions).**Transportation:** Non-hazardous for transport under sealed condition; avoid high temperature, sunlight and collision during transportation; use refrigerated transport for long-distance shipping.

7. Safety & Protection

- The product is a synthetic steroid hormone, avoid direct skin contact and dust inhalation during handling.
- Wear nitrile rubber gloves, safety glasses and dust mask for large-scale handling or prolonged contact.
- In case of skin contact: Rinse the affected area with plenty of soap and water for 5 minutes; remove contaminated clothing and wash before reuse.
- In case of eye contact: Rinse eyes thoroughly with plenty of running water for 10-15 minutes; consult a doctor if irritation persists.
- Do not ingest; if accidentally swallowed, rinse mouth with water and seek medical advice immediately.

8. Quality Assurance

- The product is manufactured in accordance with ISO 9001 quality management system and pharmaceutical raw material production specifications.
- Each batch of product is fully tested and accompanied by a Certificate of Analysis (COA) to ensure compliance with industrial standards.
- Provide professional technical support for product application, including formulation optimization, solubility guidance and quality control solutions.
- Undertake quality responsibility for qualified products under normal storage and use conditions.