

## Safety Data Sheet (MSDS)

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

**Product Name: Clomifene Citrate** Revision Date: **22 FEB 2026**

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

#### 1.1 Product Identifiers

- Product Name: Clomifene Citrate; Clomiphene Citrate
- Product Number: CC-20260222
- Brand: SIGALD
- CAS-No.: 50-41-9
- Synonyms: (Z)-2-[4-(2-Chloro-1,2-diphenylethenyl)phenoxy]ethanamine citrate; Selective Estrogen Receptor Modulator (SERM)

#### 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 gynecological ovulation-inducing drugs; raw material for oral formulations of female infertility (anovulation); pharmaceutical R&D reference reagent for reproductive pharmacology research.
- Uses Advised Against: Not for direct human use in raw form; no non-pharmaceutical industrial use; avoid use in cosmetics/food products; do not use in unformulated reproductive system preparations for clinical use.

### SECTION 2: Hazards Identification

| Summary of Emergency Measures | White crystalline powder. Harmful if swallowed. Causes mild skin irritation and serious eye irritation. May cause respiratory irritation in sensitive individuals. After inhalation: Move to fresh air and rest. In case of skin contact: Rinse with plenty of water and mild soap for 5-10 minutes. After eye contact: Rinse with plenty of water for at least 15 minutes and call a doctor. After swallowing: Rinse mouth with water, do not induce vomiting; consult a doctor if unwell. Non-combustible. No explosion risk. | |---|

#### 2.1 GHS Classification

- Acute toxicity, oral (Category 4); Skin irritation (Category 2); Serious eye irritation (Category 2A); Specific target organ toxicity - single exposure (Reproductive system, Liver, Category 3)

#### 2.2 GHS Label Elements

- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H315: Causes skin irritation
  - H319: Causes serious eye irritation
  - H335: May cause respiratory irritation
  - H373: May cause damage to organs (Reproductive system, Liver) through prolonged or repeated exposure
- Precautionary Statements:
  - P264: Wash skin 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 or doctor/physician if you feel unwell
  - P302+P352: If on skin: Wash with plenty of water and soap



# NEWAY SINOPHC TECH. LIMITED

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- P305+P351+P338+P312: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor/physician if you feel unwell
- P332+P313: If skin irritation occurs: Get medical advice/attention
- P405: Store locked up
- P501: Dispose of contents/container to an approved waste disposal plant

## 2.3 Physical and Chemical Hazards

- Non-combustible; no explosive/oxidizing properties under normal storage and handling conditions. No hazardous polymerization will occur.
- ## 2.4 Health Hazards
- Acute: Swallowing causes dizziness, gastrointestinal discomfort, menstrual irregularities; skin contact leads to redness, itching; eye contact causes severe conjunctival redness, corneal irritation; dust inhalation causes cough, nasal irritation in sensitive individuals.
  - Chronic: Prolonged exposure may cause mild reproductive system and hepatic dysfunction, reversible with strict protective measures and symptomatic treatment.
- ## 2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC<sub>50</sub> = 480 mg/L for zebrafish); fully biodegradable in natural environment; low bioaccumulation potential with no persistent residues.
- ## 2.6 Other Hazards
- No additional hazards identified based on current scientific data.

## SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance** | 3.1 Main Components | Clomifene Citrate (100%) | |---| ---  
| | Formula | C<sub>26</sub> H<sub>28</sub> ClNO<sub>7</sub> · C<sub>6</sub> H<sub>8</sub> O<sub>7</sub> | | Molecular Weight | 609.09 g/mol | | CAS-No.: | 50-41-9 | | EC-No.: | 200-035-3 |

Hazardous Ingredients  
表格

Component	Classification	Concentration (w/w)
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Clomifene Citrate GHS Category 4/2/2A/3 100%

## SECTION 4: First Aid Measures

### 4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately, keep at rest in a comfortable breathing position. Monitor respiratory status; call a doctor if cough or nasal irritation persists.
- In Case of Skin Contact: Immediately remove all contaminated clothing and shoes. Rinse skin with plenty of running water and mild soap for 5-10 minutes. Seek medical advice if irritation/rash persists for more than 24 hours.
- In Case of Eye Contact: **IMMEDIATE MEDICAL ATTENTION RECOMMENDED.** Hold eyelids open and rinse thoroughly with plenty of running water for at least 15 minutes. Remove contact lenses if present. Do not rub eyes. Call a POISON CENTER/ophthalmologist if irritation or blurred vision occurs.
- If Swallowed: Rinse mouth with water. Do not induce vomiting unless directed by a doctor. Monitor reproductive and hepatic function; call a POISON CENTER/doctor immediately if dizziness, abdominal pain or menstrual abnormalities occur.

### 4.2 Most Important Symptoms and Effects

- Acute: Dizziness, gastrointestinal discomfort (swallowed); skin erythema, pruritus (contact); severe eye irritation, blurred vision (contact); cough, nasal irritation (inhalation).
  - Delayed: Mild reproductive system and hepatic dysfunction may occur 24-48 hours after excessive ingestion; reversible with symptomatic treatment.
- ### 4.3 Indication of Immediate Medical Attention
- Severe swallowing exposure with persistent reproductive/hepatic symptoms, severe eye contact, prolonged respiratory irritation require **immediate professional medical attention.**

## SECTION 5: Firefighting Measures

### 5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO<sub>2</sub>), dry chemical powder.

- Unsuitable Extinguishing Media: No limitations of extinguishing agents.5.2 Special Hazards Arising from the Substance
- Non-combustible; slight decomposition at high temperature (>300°C) produces low-toxic chlorine-containing and nitrogen-containing fumes; no toxic/explosive gases released under normal fire conditions.5.3 Advice for Firefighters
- Wear self-contained breathing apparatus (SCBA) and full chemical-resistant fire-fighting protective gear if decomposition fumes occur during fire.
- Keep a safe distance from the fire scene; prevent fire-extinguishing water from entering municipal sewers or natural water bodies.
- Monitor hepatic and reproductive function of firefighters after exposure to decomposition fumes.

## SECTION 6: Accidental Release Measures

### 6.1 Personal Precautions

- Wear N95 dust mask, chemical-resistant nitrile gloves, safety goggles and impermeable lab coat. Ensure good ventilation at the spill site and evacuate all non-essential personnel.
- Avoid inhaling dust and prolonged contact with spilled powder; clean up immediately to prevent dust spreading.

### 6.2 Environmental Precautions

- Prevent spilled powder from entering sewers, rivers, lakes or soil. Cover the spill with inert material (sand/vermiculite) to avoid dust spreading and environmental contamination.

### 6.3 Methods and Materials for Containment and Cleaning Up

- Small Spill: Gently sweep up with a clean dry brush, collect into a sealed HDPE plastic container for professional hazardous waste disposal. Do not blow or vacuum the powder.
- Large Spill: Contain the spill with sandbags/dikes, transfer to a sealed HDPE drum with clear hazard labels, and hand over to a licensed hazardous waste treatment company. Do not wash the spill into drains or water bodies.

### 6.4 Reference to Other Sections

For waste disposal, see Section 13.

## SECTION 7: Handling and Storage

### 7.1 Precautions for Safe Handling

- Operate in a well-ventilated dust-free negative pressure fume hood; use dust-free operation tools to avoid generating dust during weighing and mixing.
- Wear the specified PPE for all handling operations; no eating, drinking, smoking or phone use in the work area.
- Wash hands, face and exposed skin thoroughly with soap and water after handling; keep the work area clean and dry.
- Avoid contact with strong acids, strong bases, oxidizing agents and high-temperature environments; do not mix with other pharmaceutical raw materials without professional guidance.

### 7.2 Conditions for Safe Storage

- Storage Conditions: Store in a **cool, dry, dark and locked** pharmaceutical warehouse. Temperature  $\leq 25^{\circ}\text{C}$ , relative humidity  $\leq 60\%$ . Keep the container tightly sealed with aluminum foil to prevent hygroscopy, light degradation and contamination.
- Incompatibilities: Strong acids (HCl,  $\text{H}_2\text{SO}_4$ ), strong bases (NaOH, KOH), oxidizing agents ( $\text{H}_2\text{O}_2$ ,  $\text{KMnO}_4$ ), heavy metal salts, reproductive/hepatic toxic pharmaceutical excipients.
- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from all other pharmaceutical raw materials, food, feed and cosmetics; place in a dedicated toxic substance storage area with warning signs; store away from other gynecological/reproductive system drugs.

## SECTION 8: Exposure Controls/Personal Protection

### 8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal strict control limit:  $0.05 \text{ mg/m}^3$  (8-hour TWA, dust) (due to reproductive/hepatic/irritant effects).

- Biological Limit Value (BLV): N/A.8.2 Exposure Controls
- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency particulate air (HEPA) filter for all dust-generating operations; dust collection system with emission concentration  $\leq 0.02 \text{ mg/m}^3$ .
- Personal Protective Equipment (PPE):
  - Eye/Face Protection: Chemical-resistant safety goggles (mandatory for all operations); full face shield for large-scale handling.
  - Skin Protection: Chemical-resistant nitrile rubber gloves (thickness  $\geq 0.20 \text{ mm}$ ), impermeable anti-chemical lab coat, protective shoe covers.
  - Respiratory Protection: N95 dust mask for routine small-scale operations; powered air-purifying respirator (PAPR) for large-scale weighing/mixing.
  - Hand Protection: Replace gloves immediately if damaged, punctured or contaminated; change gloves every 2 hours for continuous operation.

## SECTION 9: Physical and Chemical Properties

9.1 Basic Physical and Chemical Propertiesa) Physical State: Solid (crystalline powder)b) Color: White to off-whitec) Odor: Practically odorlessd) Melting Point/Freezing Point: 110-116°C (decomposes)e) Boiling Point: Not applicable (decomposes before boiling)f) Flammability: Non-combustibleg) Flammability Limits: Not applicableh) Flash Point: Not applicablei) Autoignition Temperature:  $> 450^\circ\text{C}$ j) Decomposition Temperature:  $\geq 300^\circ\text{C}$  (mild decomposition, produces low-toxic fumes)k) pH Value: 3.0-5.0 (1% aqueous suspension, 25°C)l) Viscosity: Not applicable (solid)m) Solubility: Freely soluble in methanol, ethanol, dimethyl sulfoxide (DMSO); slightly soluble in water, chloroform; insoluble in ethern) Partition Coefficient (log P, n-octanol/water): 4.2 (25°C)o) Vapor Pressure (25°C):  $< 0.0001 \text{ hPa}$ p) Density (25°C): 1.24-1.28  $\text{g/cm}^3$  (bulk density)q) Particle Size: 95% passing 100 meshr) Explosive Properties: Not explosives) Oxidizing Properties: Nonet) Hygroscopy: Slightly hygroscopic, sensitive to light

## SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions ( $\leq 25^\circ\text{C}$ , dry, dark, sealed); stable under standard pharmaceutical processing temperature ( $\leq 60^\circ\text{C}$ ).10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; stable in weak acidic environment, mild hydrolysis in strong alkaline environment.10.3 Conditions to Avoid: High temperature ( $> 300^\circ\text{C}$ ), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock, strong alkaline environment.10.4 Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts, reducing agents, alkaline pharmaceutical excipients, reproductive/hepatic toxic drugs.10.5 Hazardous Decomposition Products: Carbon dioxide, water vapor, low-toxic chlorine-containing and nitrogen-containing fumes (at high temperature complete combustion/decomposition); non-toxic Clomifene Citrate derivatives produced by alkaline hydrolysis.

## SECTION 11: Toxicological Information

### 11.1 Toxicological Effects

- Acute Toxicity (**Selective Estrogen Receptor Modulator (SERM) pharmaceutical raw material**):
  - Oral (Rat,  $\text{LD}_{50}$ ): 750  $\text{mg/kg}$  (Harmful)
  - Dermal (Rabbit,  $\text{LD}_{50}$ ):  $> 2000 \text{ mg/kg}$  (Non-hazardous)
  - Inhalation (Rat,  $\text{LC}_{50}$ ): 5.5  $\text{mg/m}^3$  (4-hour exposure, Harmful)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - moderate redness, edema and rash (Category 2), reversible within 7 days with treatment.
- Eye Irritation/Damage: Rabbit eye test - severe conjunctival redness and mild corneal opacity (Category 2A), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - mild bronchial irritation, cough at low dust concentrations ( $\geq 0.30 \text{ mg/m}^3$ ), no persistent respiratory damage.
- Mutagenicity: Ames test, chromosome aberration test - negative; no mutagenic effects.
- Carcinogenicity: IARC Classification - Group 3 (not classifiable as to carcinogenicity to humans).

- Reproductive Toxicity: No adverse reproductive/developmental effects in animal tests at clinical relevant doses; use with caution in pregnant women (contraindicated in first trimester).
- Specific Target Organ Toxicity: **Reproductive system and liver** are the main target organs; oral administration causes mild reproductive and hepatic dysfunction at clinical doses; no damage to other organs with standard protective measures.
- Allergenicity: No significant sensitizing effects in animal tests and clinical research data.

## SECTION 12: Ecological Information

### 12.1 Toxicity

- Fish (Zebrafish, 96h LC<sub>50</sub>): 480 mg/L
- Daphnia (48h EC<sub>50</sub>): 460 mg/L
- Freshwater Algae (72h EC<sub>50</sub>): 510 mg/L
- 12.2 Persistence and Degradability: Biodegradable (BOD<sub>5</sub>/COD = 0.65); degraded by microorganisms in aquatic and soil environments within 14-20 days, no persistent residues.
- 12.3 Bioaccumulative Potential: Low (log P = 4.2); no significant bioaccumulation in aquatic organisms and food chain due to rapid biodegradation.
- 12.4 Mobility in Soil: Moderate mobility; weak adsorption to soil organic matter (K<sub>oc</sub> = 200), slight leaching risk to groundwater (mitigated by biodegradation).
- 12.5 PBT/vPvB Assessment: Not classified as PBT/vPvB substances.
- 12.6 Other Adverse Effects: No known adverse effects on soil microorganisms and terrestrial plants at low concentrations; high concentration may inhibit the growth of aquatic beneficial bacteria (temporary, reversible).

## SECTION 13: Disposal Considerations

### 13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is classified as **toxic hazardous waste**; must be disposed of by licensed hazardous waste treatment facilities via high-temperature incineration (≥800°C) with flue gas treatment (to remove chlorine-containing and nitrogen-containing fumes).
- Packaging Waste: Rinse packaging with water and ethanol to remove residual powder, then dispose of as toxic hazardous waste; do not recycle or reuse any contaminated packaging.
- Unused Product: Do not discharge to the environment; incinerate with professional waste treatment companies in accordance with local national and international toxic waste regulations.
- Disposal Compliance: Comply with national and local hazardous waste disposal regulations (e.g., China HW02, EU EWC 080102, US RCRA Subtitle C).

## SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 2811

14.2 UN Proper Shipping Name: Toxic solid, organic, n.o.s. (Clomifene Citrate)

14.3 Transport Hazard Class: 6.1 (Toxic substances)

14.4 Packaging Group: III (Minor hazard)

14.5 Environmental Hazards: IMDG Marine Pollutant: **No**

14.6 Special Precautions for Transport

- Transport in sealed HDPE pharmaceutical-grade drums with aluminum foil inner lining and locked cover; affix standard Class 6.1 toxic hazard labels and product identification labels (mark SERM/gynecology/reproductive system/irritant risk warning).
- Transport temperature ≤ 30°C; avoid direct sunlight, rain, collision, extrusion and rough handling during transport (light protection mandatory).
- Do not transport with food, feed, cosmetics, aquatic products and alkaline pharmaceutical raw materials; transport in a dedicated compartment of specialized hazardous chemical vehicles; separate from reproductive/hepatic toxic drugs.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations for Class 6.1 toxic substances; provide MSDS and transport approval documents for customs clearance; attach a warning note for gynecological pharmaceutical intermediate and irritant risk.

## SECTION 15: Regulatory Information

### 15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 6.1 toxic chemical); Pharmaceutical Raw Material Registration Requirements for medical intermediates; Chinese Pharmacopoeia (CP) 2025 edition compliance; Special Control of Toxic Chemicals Regulations.

- EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Warning); European Pharmacopoeia (EP) 10.0 compliance; ADR/RID Class 6.1 transport regulations.
- US: TSCA (listed on the TSCA Inventory); DOT Class 6.1 toxic material; FDA (compliant with pharmaceutical intermediate quality standards for gynecological drugs); United States Pharmacopeia (USP) 47 compliance; RCRA toxic waste regulations.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Japanese Poisonous and Deleterious Substances Control Law.15.2 Additional Regulatory Requirements
- Provide English MSDS, COA and toxic chemical transport approval documents for customs clearance; apply for a special hazardous chemical storage license for on-site storage; provide product quality test reports and pharmacopoeia compliance certificates for pharmaceutical production use; mark SERM and gynecological/reproductive system characteristics on all product documents.

### SECTION 16: Other Information

- Further Information: This MSDS is based on current scientific and regulatory knowledge, complying with GB/T 16483, GB/T 17519 and GHS Rev.9 standards. It is for professional occupational health and safety use only for trained operators, transport personnel and storage managers. Key characteristic: **Selective Estrogen Receptor Modulator (SERM) gynecological pharmaceutical intermediate, mild reproductive/hepatic toxicity, low environmental toxicity.**
- Revision Date: 22 FEB 2026