



NEWAY SINOPHC TECH. LIMITED

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Safety Data Sheet (MSDS) - Fentanyl Citrate

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0
Product Name: Fentanyl Citrate
CAS Number: 297-19-8
Product Number: FC-20260215
Brand: SIGALD
Revision Date: 15 FEB 2026
Supplier: NEWAY SINOPHC TECH. LIMITED
Address: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE
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Emergency Telephone: +86-021-50350029 (24h Narcotic Drug Emergency Response)

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

1.1 Product Identifiers

- Product Name: Fentanyl Citrate
- CAS-No.: 297-19-8
- MDL No.: MFCD00012065
- Synonyms: N-Phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]propanamide citrate; Fentanyl hydrogen citrate
- Product Number: FC-20260215

1.4 Relevant Identified Uses and Uses Advised Against

- **Identified Uses:** Pharmaceutical raw material for the production of clinical analgesic/anesthetic preparations (only for licensed pharmaceutical enterprises).
- **Uses Advised Against:** Non-pharmaceutical use, direct clinical administration (raw material only), household use, unauthorized processing/sale, use in food/cosmetic production, and unlicensed clinical use.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 2)
- Acute toxicity, dermal (Category 2)
- Acute toxicity, inhalation (dust/mist, Category 2)
- Narcotic effects (Category 1)
- Physical dependence (Category 1)
- Specific target organ toxicity - single exposure (central nervous system, Category 2)
- Serious eye irritation (Category 2)

2.2 GHS Label Elements

- **Hazard Pictograms:** Skull and crossbones (☠), Exclamation mark (!)
- **Signal Word:** Danger
- **Hazard Statements:**
 - H300: Fatal if swallowed
 - H310: Fatal in contact with skin
 - H330: Fatal if inhaled
 - H360: May damage fertility or the unborn child
 - H370: Causes damage to organs (central nervous system, respiratory system)
 - H319: Causes serious eye irritation
 - H413: May cause long-term adverse effects in the aquatic environment

Precautionary Statements:

- P201: Obtain special instructions before use
- P260: Do not breathe dust/fume/gas/mist/vapors/spray
- P270: Do not eat, drink or smoke when using this product
- P280: Wear protective gloves/eye protection/face protection/respiratory protection
- P301+P310: If swallowed: Immediately call a POISON CENTER/doctor
- P302+P310: If on skin: Immediately call a POISON CENTER/doctor
- P304+P340: If inhaled: Remove person to fresh air and keep comfortable for breathing
- P405: Store locked up
- P501: Dispose of contents/container in accordance with local/national/international regulations

2.3-2.6 Hazards Summary



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- **Physical/Chemical Hazards:** Non-flammable, non-explosive, non-oxidizing under normal use; stable at recommended storage temperature.
- **Health Hazards:** Inhalation/skin contact/swallowing causes severe central nervous system depression (drowsiness, coma, respiratory arrest) and is fatal in small doses; long-term exposure causes severe physical dependence; serious eye irritation; may damage fertility.
- **Environmental Hazards:** Toxic to aquatic organisms; may cause long-term adverse effects in water bodies; not biodegradable; has bioaccumulation potential.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture:** Pure pharmaceutical grade substance (100% w/w)
- **Active Ingredient:** Fentanyl Citrate (CAS:297-19-8) | Hazard classification: see Section 2
- **No other ingredients/additives**

SECTION 4: First Aid Measures

4.1 First-Aid Measures

- **Inhaled:** Immediately remove victim to fresh air; keep respiratory tract open. If breathing stops, perform artificial respiration (avoid mouth-to-mouth) and administer oxygen; **call a poison center/physician at once** and give opioid antagonist (naloxone) under medical supervision.
- **Skin Contact:** Immediately remove contaminated clothing and shoes; rinse skin with plenty of soap and running water for 15-20 minutes. **Call a poison center/physician at once**; monitor for respiratory depression and administer naloxone if needed.
- **Eye Contact:** Immediately rinse eyes thoroughly with plenty of sterile water for injection for 15-20 minutes (lift upper/lower eyelids); remove contact lenses if worn. **Consult an ophthalmologist immediately**; continue to monitor for systemic effects.
- **Swallowed:** Do not induce vomiting; rinse mouth with water. **Immediately call a poison center/doctor**; administer naloxone intravenously under medical supervision for respiratory depression; provide respiratory support if needed.

4.2 Most Important Symptoms

Acute: Rapid onset of drowsiness, dizziness, confusion, respiratory depression, bradycardia, hypotension, coma; fatal within minutes in severe cases. Delayed: Physical dependence with short-term exposure; chronic respiratory system damage; fertility damage.

4.3 Medical Attention

Inform the physician of the product name (Fentanyl Citrate) and CAS number; administer opioid antagonists (naloxone/naltrexone) as the first-line treatment; provide continuous respiratory and cardiovascular support until stable.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- **Suitable:** Dry powder, carbon dioxide (CO₂), foam; water spray (for cooling fire-exposed containers).
- **Unsuitable:** No restrictions; avoid direct high-pressure water on bulk powder (to prevent dust spread and inhalation).

5.2 Special Hazards

No hazardous combustion products under normal fire conditions; thermal decomposition at high temperature (>200°C) produces small amounts of carbon monoxide (CO), nitrogen oxides (NO_x) and aromatic hydrocarbons.

5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and full chemical protective gear; fight fire from upwind; cool containers with water spray until fire is out; prevent fire water from entering water bodies/soil (environmental protection); collect and dispose of fire debris as hazardous waste.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear full level C PPE (nitrile rubber gloves, chemical safety goggles, full face shield, N95+ respirator, impermeable protective clothing); avoid any contact with spilled material.



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- Evacuate all non-essential personnel to a safe distance; set up a restricted warning zone; operate in a well-ventilated area with negative pressure.
- The product is a Class I narcotic controlled drug—**immediately report the spill to the drug regulatory department and public security organ.**

6.2 Environmental Precautions

Prevent spilled powder/leachate from entering sewers, rivers, lakes, soil and groundwater; use inert absorbents to cover and contain spilled material to avoid environmental contamination.

6.3 Containment and Cleaning Up

- **Small Spill:** Cover with inert absorbent (sand/diatomite); collect into a sealed GMP-compliant hazardous waste container with a label; lock up and report for disposal.
- **Large Spill:** Contain with dikes; collect with an anti-static vacuum cleaner into a sealed stainless steel drum; seal and mark the drum; report to relevant departments for unified disposal by licensed professionals.
- Do not reuse contaminated absorbents; do not wash spilled material into drainage systems; decontaminate the spill area with neutral detergent and rinse with water.

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate only in GMP-certified workshops by trained personnel with narcotic drug operation licenses; set up a dedicated, closed operation area with negative pressure dust collection.
- Use closed feeding and mixing equipment to avoid dust generation/inhalation; no manual direct contact with the product.
- Do not eat, drink or smoke during handling; wash hands/face thoroughly with soap and water after operation; take a shower if necessary.
- Avoid contact with strong acids, strong bases, oxidizing agents and reducing agents (to prevent degradation); record all operation processes in detail (narcotic drug account management).

7.2 Safe Storage

- **Storage Conditions:** 2~8°C (refrigerated, dark place); tightly sealed HDPE/aluminum foil/stainless steel containers; relative humidity ≤60%.
- **Incompatibilities:** Strong acids (pH<3), strong bases (pH>10), oxidizing agents (H₂O₂, KMnO₄), reducing agents (sodium borohydride), heavy metal salts.
- **Storage Class:** Class I narcotic controlled pharmaceutical raw material (locked storage in a dedicated, alarm-equipped narcotic drug warehouse with 24h video monitoring).
- **Shelf Life:** 24 months (unopened, 2~8°C refrigeration); 6 months after opening (sealed, refrigerated, and used up as soon as possible).

SECTION 8: Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits

- No official national/international OEL for Fentanyl Citrate; use **the strictest exposure control measures** (no detectable exposure in the workplace).
- Biological limit: No established standard; regular physical examination for operators (focus on respiratory and nervous systems).

8.2 Exposure Controls

- **Engineering Controls:** Closed operation system, negative pressure dust collection, local exhaust ventilation, GMP workshop air filtration (HEPA filter), pressure difference control.
- **Personal Protective Equipment (PPE):**
 - Eye/Face: Chemical safety goggles + full face shield (mandatory for all operations)
 - Skin: Nitrile rubber gloves (thickness ≥0.18mm) + impermeable protective clothing + anti-static shoes
 - Respiratory: N95 respirator + organic vapor cartridge (for normal operation); SCBA (for emergency spills/leaks)
 - Other: Disposable hairnet/mask/gown, hand washing station with emergency eye wash/shower equipment.

- **Hygiene:** Dedicated changing room for work clothes; no food/drinks in the operation area; regular occupational health checkups for operators.

SECTION 9: Physical and Chemical Properties

表格

Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	148 ~ 151 °C
Boiling Point	Decomposes before boiling (>200 °C)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>300 °C
Solubility	Freely soluble in water; soluble in ethanol; slightly soluble in ether/chloroform
pH Value (1% aqueous solution, 25 °C)	4.0 ~ 6.0
Density (25 °C, solid)	1.24 g/cm ³
Vapor Pressure (25 °C)	<0.0001 hPa (negligible)
Particle Size	95% pass through 100-mesh sieve (pharmaceutical grade)
Stability	Stable at 2~8 °C; decomposes at >25 °C (long-term) and >200 °C (thermal)

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended storage conditions (2~8 °C, dark, sealed)**; no degradation for the shelf life.

10.2-10.5 Reactivity Summary

- No hazardous reactions under normal use/handling conditions.
- **Conditions to Avoid:** High temperature (>25 °C), direct sunlight, moisture, contact with strong acids/alkalis/oxidizing/reducing agents.
- **Incompatible Materials:** Concentrated HCl/H₂SO₄, NaOH/KOH, hydrogen peroxide, potassium permanganate, sodium borohydride, silver nitrate.
- **Hazardous Decomposition Products:** Carbon monoxide (CO), nitrogen oxides (NO_x), aromatic hydrocarbons (at >200 °C).
- No polymerization under normal conditions.

SECTION 11: Toxicological Information

11.1 Key Toxicological Data

- **Acute Toxicity:**
 - Oral (Rat, LD₅₀): 0.3 mg/kg bw
 - Dermal (Rabbit, LD₅₀): 0.5 mg/kg bw
 - Inhalation (Rat, LC₅₀, 4h): 0.01 mg/m³ (dust)
- **Skin Irritation (Rabbit):** Mild irritation (4h exposure)
- **Eye Irritation (Rabbit):** Severe irritation (24h exposure, reversible conjunctivitis/corneal damage)
- **Sensitization:** No skin/respiratory sensitization (Guinea pig test)
- **Carcinogenicity:** IARC Class 3 (Not classifiable as to its carcinogenicity to humans)
- **Reproductive Toxicity:** Causes fertility damage and fetal malformation (rat/mouse tests at low doses); classified as a reproductive toxin.
- **Target Organ Toxicity:** Central nervous system (severe depression), respiratory system (respiratory arrest), cardiovascular system (bradycardia/hypotension).

11.2 Toxicity Summary

Fentanyl Citrate is an ultra-high potency opioid with fatal acute toxicity in small doses; the main toxic effect is severe central nervous system and respiratory depression. Long-term exposure causes irreversible physical dependence and reproductive damage; local effects

include serious eye irritation. Opioid antagonists (naloxone) are the specific antidote for acute poisoning.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC₅₀, 96h): 0.05 mg/L
- Daphnia (EC₅₀, 48h): 0.02 mg/L
- Algae (EC₅₀, 72h): 0.08 mg/L
- **Conclusion:** Highly toxic to aquatic organisms; fatal to small aquatic organisms at trace concentrations.

12.2-12.7 Ecological Properties

- **Persistence/Degradability:** Not biodegradable (BOD₅/COD <0.05) in aquatic environments.
- **Bioaccumulative Potential:** Very high (log Kow=5.1; bioaccumulation factor (BAF) >10,000 in fish).
- **Mobility in Soil:** Low (strongly adsorbs to soil organic matter; no leaching to groundwater).
- **PBT/vPvB:** Classified as PBT (Persistent, Bioaccumulative, Toxic) and vPvB (very Persistent, very Bioaccumulative).
- **Other Adverse Effects:** Inhibits the growth of soil microorganisms; no eutrophication risk.

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- **Product Waste:** Classified as **hazardous pharmaceutical waste** and **Class I narcotic drug waste**; dispose of by licensed narcotic drug waste treatment enterprises (incineration at >1000°C with flue gas purification treatment).
- **Packaging Waste:** Rinse packaging with ethanol (3 times); collect the rinse solution and incinerate with the product waste; decontaminate the clean packaging and dispose of as pharmaceutical hazardous waste (no recycling).
- **Do not dispose of with household waste, general industrial waste or medical waste;** do not discharge into sewers/rivers/soil/groundwater.

13.2 Disposal Regulations

Comply with China's **Hazardous Waste Pollution Control Law, Narcotic Drug Administration Law, Pharmaceutical Waste Disposal Standards** and EU **REACH/WEEE** regulations.

SECTION 14: Transport Information

14.1-14.7 Transport Details

- **UN Number:** UN 1544 (Opioid analgesics, solid, n.o.s.)
- **UN Proper Shipping Name:** Fentanyl Citrate (narcotic drug, solid, toxic)
- **Transport Hazard Class:** 6.1 (Toxic substances)
- **Packaging Group:** I (Extremely dangerous)
- **Marine Pollutant:** Yes (P)
- **Special Transport Requirements:**
 1. Classified as **Class I narcotic controlled drug**; transport with **narcotic drug transport license** and **hazardous chemical transport license** (issued by drug regulatory and emergency management departments).
 2. Refrigerated transport (2~8°C) with real-time temperature monitoring; use sealed, shockproof, moisture-proof, light-proof and tamper-proof packaging.
 3. Load/unload gently; avoid package damage; store separately from food, feed, strong acids/alkalis and oxidizing agents in the transport vehicle; set up a dedicated loading area.
 4. The transport vehicle is equipped with fire-fighting equipment, emergency spill treatment materials and opioid antagonists (naloxone); the driver and escort have professional training certificates for narcotic drugs.
- **International Transport:** Comply with **UN Single Convention on Narcotic Drugs (1961)** (Schedule I), IATA/IMDG/ADR regulations for Class 6.1 toxic substances.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China:**

- Narcotic Drug Administration Law (Class I narcotic controlled drug)
- Hazardous Chemical Safety Management Regulation (Class 6.1 toxic substance)
- Chinese Pharmacopoeia (2025 Edition)
- GMP for Pharmaceutical Raw Materials
- Occupational Disease Prevention and Control Law

- **International:**

- UN Single Convention on Narcotic Drugs (1961) (Schedule I)
- GHS Rev.9 (hazard classification)
- USP 45 / EP 10.0 (pharmacopoeial standards)
- REACH (EU) (registered; listed in SVHC Candidate List)
- TSCA (US) (listed on the TSCA Inventory)
- IATA/IMDG/ADR (Class 6.1 transport regulations)

15.2 Other Requirements

- Production/sale/use requires **special licenses** for narcotic drugs (issued by the National Medical Products Administration).
- Occupational operation requires professional narcotic drug operation training and certification; regular occupational health checkups and psychological evaluation for operators.
- The whole process is subject to strict supervision by drug regulatory and public security departments; complete account management and traceability system.

SECTION 16: Other Information

- **MSDS Validity:** This MSDS is valid for 3 years from the revision date (15 FEB 2026) unless the product formula or hazard information changes.
- **Disclaimer:** This MSDS is based on current scientific and technical knowledge; the supplier is not liable for any damage caused by improper use, non-compliance with regulations, or unauthorized handling of the product.
- **Additional Information:** For more technical/formulation data, contact the supplier's technical department (+86-021-50350029 ext. 809).
- **Key Reminder:** This product is a **Class I narcotic controlled drug** with fatal acute toxicity; any illegal production/sale/use/transport will be subject to severe criminal liability in accordance with the law.