



NEWAY SINOPHC TECH. LIMITED

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Safety Data Sheet (MSDS) - Sufentanil

According to: GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0 **Product Name:** Sufentanil **CAS Number:** 56030-54-7 **Product Number:** SF-20260228 **Brand:** SIGALD **Revision Date:** 28 FEB 2026 **Supplier:** NEWAY SINOPHC TECH. LIMITED **Address:** RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE **Telephone/Fax:** +86-021-50350029 **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: Sufentanil
- CAS-No.: 56030-54-7
- MDL No.: MFCD00084762
- Synonyms: N-[4-(Methoxymethyl)-1-[2-(2-thienyl)ethyl]piperidin-4-yl]-N-phenylpropanamide; Sufentanil base
- Product Number: SF-20260228

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 with narcotic drug operation qualification).
- **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 1)
- Acute toxicity, dermal (Category 1)
- Acute toxicity, inhalation (dust/mist, Category 1)
- Narcotic effects (Category 1)
- Physical dependence (Category 1)
- Specific target organ toxicity - single exposure (central nervous system, respiratory system, Category 1)
- 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 severe 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

- **Physical/Chemical Hazards:** Non-flammable, non-explosive, non-oxidizing under normal use; stable at recommended storage temperature (2~8°C), degraded by strong light/heat/moisture.



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- **Health Hazards:** Inhalation/skin contact/swallowing of trace amounts causes severe central nervous system and respiratory depression (drowsiness, coma, respiratory arrest) and is fatal; long-term exposure causes severe physical and psychological dependence; serious eye irritation; may damage fertility and fetal development.
- **Environmental Hazards:** Highly toxic to aquatic organisms; may cause long-term adverse effects in water bodies; non-biodegradable; has strong bioaccumulation potential in the food chain.

SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture:** Pure pharmaceutical grade substance (100% w/w)
- **Active Ingredient:** Sufentanil (CAS:56030-54-7) | 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/naltrexone) intravenously under medical supervision (repeated doses required due to long half-life of sufentanil).
- **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 vital signs for 4-6 hours 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 toxic effects (even mild eye contact may lead to systemic absorption).
- **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 continuous respiratory and cardiovascular support for at least 6 hours (due to prolonged drug effect).

4.2 Most Important Symptoms

Acute: Rapid onset of drowsiness, dizziness, confusion, bradycardia, hypotension, severe respiratory depression, coma; fatal within minutes in severe cases (trace exposure). Delayed: Severe physical and psychological dependence with short-term exposure; chronic respiratory system damage; fertility and fetal development damage; recurrent eye irritation.

4.3 Medical Attention

Inform the physician of the product name (Sufentanil) and CAS number; emphasize the **ultra-high potency and long half-life** of the drug; administer opioid antagonists (naloxone) as the first-line treatment with repeated doses; provide continuous respiratory and cardiovascular support until the patient is completely stable (at least 6-8 hours).

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 by firefighters).

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), sulfur dioxide (SO₂) 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 narcotic drug waste.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions



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- 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 (even trace amounts).
- Evacuate all non-essential personnel to a safe distance (at least 50 meters); set up a restricted warning zone with obvious narcotic drug hazard signs; operate in a well-ventilated area with negative pressure dust collection.
- The product is a Class I narcotic controlled drug—**immediately report the spill to the drug regulatory department and public security organ** (within 1 hour).

6.2 Environmental Precautions

Prevent spilled powder/leachate from entering sewers, rivers, lakes, soil and groundwater; use inert absorbents (sand/diatomite) to cover and contain spilled material to avoid environmental contamination and aquatic organism poisoning.

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 clear narcotic drug label; lock up and report for unified disposal by relevant departments.
- **Large Spill:** Contain with dikes; collect with an anti-static vacuum cleaner (special for narcotic drugs) into a sealed stainless steel drum; seal and mark the drum with narcotic drug hazard information; report to drug regulatory and public security departments for disposal by licensed professional teams (no on-site disposal allowed).
- Do not reuse contaminated absorbents; do not wash spilled material into drainage systems; decontaminate the spill area with neutral detergent and rinse with water; collect the rinse water for hazardous waste treatment.

SECTION 7: Handling and Storage

7.1 Safe Handling

- Operate only in GMP-certified workshops by trained personnel with **Class I narcotic drug operation license**; set up a dedicated, closed operation area with negative pressure dust collection and 24h video monitoring.
- Use closed feeding and mixing equipment to avoid dust generation/inhalation; no manual direct contact with the product (even with gloves).
- Do not eat, drink or smoke during handling; wash hands/face thoroughly with soap and water for at least 5 minutes after operation; take a shower if the body is contaminated.
- Avoid contact with strong acids, strong bases, oxidizing agents, reducing agents and metal ions (to prevent degradation); record all operation processes in detail (narcotic drug account management with double signature).

7.2 Safe Storage

- **Storage Conditions:** 2 ~ 8°C (refrigerated, dark place); nitrogen-filled tight sealing in brown glass/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 (Fe³⁺, Cu²⁺), strong light and high temperature.
- **Storage Class:** Class I narcotic controlled pharmaceutical raw material (locked storage in a dedicated, alarm-equipped narcotic drug warehouse with 24h video monitoring and double lock management).
- **Shelf Life:** 24 months (unopened, nitrogen-filled, 2~8°C refrigeration); 3 months after opening (sealed, refrigerated, and used up as soon as possible with strict account recording).

SECTION 8: Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits

- No official national/international OEL for Sufentanil; use **the strictest exposure control measures** (no detectable exposure in the workplace, trace exposure is fatal).
- Biological limit: No established standard; regular physical examination for operators (focus on respiratory, nervous and reproductive systems); psychological evaluation for long-term operators.

8.2 Exposure Controls

- **Engineering Controls:** Closed operation system, negative pressure dust collection (air exchange rate ≥ 15 times/h), local exhaust ventilation, GMP workshop air filtration (HEPA filter), pressure difference control, 24h video monitoring.

- **Personal Protective Equipment (PPE):**

- Eye/Face: Chemical safety goggles + full face shield (mandatory for all operations)
- Skin: Nitrile rubber gloves (thickness $\geq 0.18\text{mm}$) + impermeable protective clothing + anti-static shoes + disposable arm covers
- Respiratory: N95 respirator + organic vapor cartridge (for normal operation); SCBA (for emergency spills/leaks)
- Other: Disposable hairnet/mask/gown, double-layer gloves for direct operation, hand washing station with emergency eye wash/shower equipment (within 5 meters of operation area).

- **Hygiene:** Dedicated changing room for work clothes (separate from daily clothes); no food/drinks in the operation area; regular occupational health checkups (quarterly) and psychological counseling for operators.

SECTION 9: Physical and Chemical Properties

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Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	96 ~ 100°C
Boiling Point	Decomposes before boiling (>200°C)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>300°C
Solubility	Freely soluble in chloroform/ethanol; soluble in acetone; slightly soluble in water
pH Value (0.1% aqueous suspension, 25°C)	5.0 ~ 7.0
Density (25°C, solid)	1.18 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 (dark, nitrogen-filled); degraded by strong light/heat (>25°C)/moisture
Refractive Index (25°C, 1% ethanol solution)	1.521 ~ 1.525

SECTION 10: Stability and Reactivity

10.1 Chemical Stability

Stable under **recommended storage conditions (2~8°C, dark, nitrogen-filled, sealed)**; no degradation for the shelf life and good compatibility with common pharmaceutical excipients (cosolvents, buffers).

10.2-10.5 Reactivity Summary

- No hazardous reactions under normal use/handling conditions (with strict protection).
- **Conditions to Avoid:** High temperature (>25°C), direct strong light, moisture, contact with strong acids/alkalis/oxidizing/reducing agents/metal ions, air exposure (oxidation).
- **Incompatible Materials:** Concentrated HCl/H₂SO₄, NaOH/KOH, hydrogen peroxide, potassium permanganate, sodium borohydride, iron(III) chloride, copper sulfate, silver nitrate.
- **Hazardous Decomposition Products:** Carbon monoxide (CO), nitrogen oxides (NO_x), sulfur dioxide (SO₂), aromatic hydrocarbons (at >200°C); photodegradation products (inactive metabolites) under strong light.
- No polymerization under normal conditions.

SECTION 11: Toxicological Information

11.1 Key Toxicological Data

- **Acute Toxicity:**
 - Oral (Rat, LD₅₀): 0.08 mg/kg bw
 - Dermal (Rabbit, LD₅₀): 0.12 mg/kg bw
 - Inhalation (Rat, LC₅₀, 4h): 0.002 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 severe fertility damage and fetal malformation (rat/mouse tests at trace doses); classified as a severe reproductive toxin (Category 1).
- **Target Organ Toxicity:** Central nervous system (severe depression), respiratory system (respiratory arrest), cardiovascular system (bradycardia/hypotension), reproductive system (fertility damage).

11.2 Toxicity Summary

Sufentanil is an **ultra-high potency opioid** with fatal acute toxicity in trace amounts; the main toxic effect is severe central nervous system and respiratory depression, which can cause death within minutes of exposure. Long-term exposure causes irreversible physical and psychological dependence and severe reproductive damage; local effects include serious eye irritation. Opioid antagonists (naloxone) are the specific antidote for acute poisoning, but **repeated doses are required** due to the long half-life of sufentanil.

SECTION 12: Ecological Information

12.1 Ecotoxicity

- Fish (Zebrafish, LC₅₀, 96h): 0.01 mg/L
- Daphnia (EC₅₀, 48h): 0.005 mg/L
- Algae (EC₅₀, 72h): 0.02 mg/L
- **Conclusion:** Extremely toxic to aquatic organisms; fatal to aquatic life at trace concentrations (even ppb level).

12.2-12.7 Ecological Properties

- **Persistence/Degradability:** Non-biodegradable (BOD₅/COD <0.01) in aquatic environments; remains stable in water for more than 6 months.
- **Bioaccumulative Potential:** Extremely high (log Kow=6.2; bioaccumulation factor (BAF) >100,000 in fish); strong biomagnification in the food chain.
- **Mobility in Soil:** Low (strongly adsorbs to soil organic matter; no leaching to groundwater, but persistent in soil for years).
- **PBT/vPvB:** Classified as PBT (Persistent, Bioaccumulative, Toxic) and vPvB (very Persistent, very Bioaccumulative) — the highest environmental hazard classification.
- **Other Adverse Effects:** Inhibits the growth and reproduction of soil microorganisms; causes population decline of aquatic invertebrates and fish.

SECTION 13: Disposal Considerations

13.1 Waste Treatment

- **Product Waste:** Classified as **hazardous pharmaceutical waste** and **Class I narcotic drug waste**; dispose of only by **licensed narcotic drug waste treatment enterprises** designated by the drug regulatory department (incineration at >1200°C with flue gas purification treatment to remove all toxic gases).
- **Packaging Waste:** Rinse packaging with ethanol (3 times) under nitrogen protection; collect the rinse solution and incinerate with the product waste; decontaminate the clean packaging and dispose of as narcotic drug hazardous waste (no recycling, no secondary use).
- **Do not dispose of with household waste, general industrial waste or medical waste**; do not discharge into sewers/rivers/soil/groundwater (strictly prohibited by environmental protection and drug regulatory laws).

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; strictly follow the national narcotic drug waste disposal procedures with complete account records and double signature confirmation.

SECTION 14: Transport Information

14.1-14.7 Transport Details

- **UN Number:** UN 1544 (Opioid analgesics, solid, n.o.s.)
- **UN Proper Shipping Name:** Sufentanil (narcotic drug, solid, highly toxic)
- **Transport Hazard Class:** 6.1 (Toxic substances, Category 1)
- **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** (dual licenses issued by drug regulatory and emergency management departments).
 2. Refrigerated transport (2~8°C) with real-time temperature monitoring (data recording for at least 1 year); use sealed, shockproof, moisture-proof, light-proof and tamper-proof packaging (brown glass/stainless steel).
 3. Load/unload gently; avoid package damage; store separately from food, feed, strong acids/alkalis, oxidizing agents and other drugs in the transport vehicle; set up a dedicated loading area with narcotic drug hazard signs.
 4. The transport vehicle is equipped with fire-fighting equipment, emergency spill treatment materials and opioid antagonists (naloxone); the driver and escort have **narcotic drug transport qualification certificates** and professional first-aid training.
 5. No mixed transport with other goods; the transport route is approved by the public security organ in advance; 24h special escort for bulk transport.
- **International Transport:** Comply with **UN Single Convention on Narcotic Drugs (1961)** (Schedule I), IATA/IMDG/ADR regulations for Class 6.1 Category 1 toxic substances; apply for international narcotic drug transport approval in advance.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- **China:**
 - Narcotic Drug Administration Law (Class I narcotic controlled drug, the strictest management level)
 - Hazardous Chemical Safety Management Regulation (Class 6.1 Category 1 highly toxic substance)
 - Chinese Pharmacopoeia (2025 Edition)
 - GMP for Pharmaceutical Raw Materials (strictest implementation standards)
 - Occupational Disease Prevention and Control Law (special occupational protection for operators)
- **International:**
 - UN Single Convention on Narcotic Drugs (1961) (Schedule I, global strict control)
 - GHS Rev.9 (hazard classification: Category 1 acute toxicity)
 - USP 45 / EP 10.0 (pharmacopoeial standards)
 - REACH (EU) (registered; listed in SVHC Candidate List due to high toxicity)
 - TSCA (US) (listed on the TSCA Inventory with strict use restrictions)
 - IATA/IMDG/ADR (Class 6.1 Category 1 transport regulations)

15.2 Other Requirements

- Production/sale/use requires **the highest level of special licenses** for narcotic drugs (issued by the National Medical Products Administration); no small-scale production or unlicensed use is allowed.
- Occupational operation requires professional narcotic drug operation training and certification; operators must pass physical and psychological examinations and receive regular professional training and counseling.
- The whole process (production, storage, transport, use, waste disposal) is subject to 24h supervision by drug regulatory, public security and environmental protection departments; complete traceability account management is required with no missing records.

SECTION 16: Other Information

- **MSDS Validity:** This MSDS is valid for 3 years from the revision date (28 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. 813) (only for licensed pharmaceutical enterprises with narcotic drug qualification).
- **Key Reminder:** This product is a **Class I narcotic controlled drug with ultra-high acute toxicity**; any illegal production/sale/use/transport/disposal will be subject to severe criminal liability in accordance with national and international laws (including imprisonment).