



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

## Safety Data Sheet (MSDS) - Alfentanil

**According to:** GB/T 16483, GB/T 17519, GHS Rev.9, USP 45, EP 10.0 **Product Name:** Alfentanil **CAS Number:** 71195-58-9 **Product Number:** AF-20260208 **Brand:** PHARMASTAND **Revision Date:** 08 FEB 2026 **Supplier:** PHARMA NEWAY CO., LTD **Address:** RM. 306, Building 5, No. 288, Aona Rd., China (Shanghai) Pilot Free Trade Zone **Telephone/Fax:** +86-021-50350039 **Emergency Telephone:** +86-021-50350039 (24h Narcotic Drug Emergency Response)

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

#### 1.1 Product Identifiers

- Product Name: Alfentanil
- CAS-No.: 71195-58-9
- MDL No.: MFCD00084706
- Synonyms: Alfentanil base; N-[1-[2-(4-ethyl-4,5-dihydro-5-oxo-1H-tetrazol-1-yl)ethyl]-4-(methoxymethyl)piperidin-4-yl]-N-phenylpropionamide
- Product Number: AF-20260208

#### 1.4 Relevant Identified Uses and Uses Advised Against

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

### SECTION 2: Hazards Identification

#### 2.1 GHS Classification

- Acute toxicity, oral (Category 4)
- Acute toxicity, dermal (Category 4)
- Acute toxicity, inhalation (dust/mist, Category 4)
- Narcotic effects (Category 2)
- Physical dependence (Category 2)
- Specific target organ toxicity - single exposure (central nervous system, Category 3)

#### 2.2 GHS Label Elements

- **Hazard Pictograms:** Skull and crossbones (☠), Exclamation mark (!)
- **Signal Word:** Warning
- **Hazard Statements:**
  - H302: Harmful if swallowed
  - H312: Harmful in contact with skin
  - H332: Harmful if inhaled
  - H361: Suspected of causing fertility damage (limited data)
  - H371: May cause damage to organs (central nervous system) through single exposure
  - H413: May cause long-term adverse effects in the aquatic environment

- **Precautionary Statements:**

- P201: Obtain special instructions before use
- P261: Avoid breathing dust/fume/gas/mist/vapors/spray
- P270: Do not eat, drink or smoke when using this product
- P271: Use only outdoors or in a well-ventilated area
- 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 soap and water
- P330: Rinse mouth
- 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:** No flammable/explosive/oxidizing properties under normal use; stable at recommended storage temperature.



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- **Health Hazards:** Inhalation/skin contact/swallowing causes central nervous system depression (drowsiness, dizziness, respiratory depression); long-term exposure may cause physical dependence; mild skin/eye irritation.

- **Environmental Hazards:** Slightly toxic to aquatic organisms; may cause long-term adverse effects in water bodies; not biodegradable.

## SECTION 3: Composition/Information on Ingredients

- **Substance/Mixture:** Pure substance (pharmaceutical grade)
- **Active Ingredient:** Alfentanil (100%, w/w) | CAS:71195-58-9 | Hazard classification: see Section 2
- **No other ingredients/additives**

## SECTION 4: First Aid Measures

### 4.1 First-Aid Measures

- **Inhaled:** Move victim to fresh air; keep respiratory tract open. If breathing is difficult, give oxygen; if respiratory arrest occurs, perform artificial respiration (avoid mouth-to-mouth) and call a poison center/physician at once.
- **Skin Contact:** Remove contaminated clothing; rinse skin with plenty of soap and running water for 10~15 minutes. If irritation persists, seek medical advice.
- **Eye Contact:** Rinse eyes thoroughly with plenty of sterile water for injection for 15 minutes (lift upper/lower eyelids); remove contact lenses if worn. Consult an ophthalmologist immediately if irritation/damage occurs.
- **Swallowed:** Do not induce vomiting; rinse mouth with water. Call a poison center/physician at once; administer opioid antagonist (e.g., naloxone) under medical supervision if respiratory depression occurs.

### 4.2 Most Important Symptoms

Acute: Drowsiness, dizziness, nausea, vomiting, respiratory depression, bradycardia, hypotension; severe cases may cause coma and death. Delayed: Physical dependence with long-term exposure; central nervous system dysfunction.

### 4.3 Medical Attention

Inform the physician of the product name (Alfentanil) and CAS number; administer symptomatic treatment (e.g., opioid antagonists, respiratory support) as soon as possible.

## SECTION 5: Firefighting Measures

### 5.1 Extinguishing Media

- **Suitable:** Dry powder, carbon dioxide (CO<sub>2</sub>), foam; water spray (for cooling fire-exposed containers).
- **Unsuitable:** No restrictions; avoid direct high-pressure water on bulk powder (to prevent dust spread).

### 5.2 Special Hazards

No hazardous combustion products; thermal decomposition at high temperature (>200°C) produces small amounts of nitrogen oxides (NO<sub>x</sub>) and carbon monoxide (CO).

### 5.3 Firefighter Advice

Wear self-contained breathing apparatus (SCBA) and full fire-fighting 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).

## SECTION 6: Accidental Release Measures

### 6.1 Personal Precautions

- Wear full PPE (nitrile gloves, safety goggles, dust mask, protective clothing); avoid contact with spilled material.
- Evacuate non-essential personnel; set up warning zones; operate in a well-ventilated area.
- The product is a controlled narcotic drug—report spills to the drug regulatory department at once.

### 6.2 Environmental Precautions

Prevent spilled powder/leachate from entering sewers, rivers, lakes, and soil; contain spilled material with inert absorbents (e.g., sand, diatomite) to avoid environmental contamination.

## 6.3 Containment and Cleaning Up

- **Small Spill:** Absorb with inert absorbent; place into a sealed GMP-compliant waste container for hazardous pharmaceutical waste disposal.
- **Large Spill:** Contain with dikes; collect with a vacuum cleaner (anti-static) into a sealed stainless steel drum; lock up and report to relevant departments for disposal.
- Do not reuse contaminated absorbents; do not wash spilled material into drainage systems.

## SECTION 7: Handling and Storage

### 7.1 Safe Handling

- Operate only in GMP-certified workshops by trained personnel with narcotic drug operation licenses.
- Use closed operation and negative pressure dust collection systems to avoid dust generation/inhalation.
- Do not eat, drink or smoke during handling; wash hands/face thoroughly with soap after operation.
- Avoid contact with strong acids, strong bases, and oxidizing agents (to prevent degradation).

### 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 (e.g., hydrogen peroxide, potassium permanganate).
- **Storage Class:** Narcotic controlled pharmaceutical raw material (locked storage in a dedicated drug warehouse with 24h monitoring).
- **Shelf Life:** 24 months (unopened, 2~8°C); 6 months after opening (sealed, refrigerated).

## SECTION 8: Exposure Controls/Personal Protection

### 8.1 Occupational Exposure Limits

- No official national/international OEL for Alfentanil; use **best practice exposure control** (closed system, dust collection).
- Biological limit: No established standard.

### 8.2 Exposure Controls

- **Engineering Controls:** Closed operation, negative pressure dust collection, local exhaust ventilation, GMP workshop air filtration.
- **Personal Protective Equipment (PPE):**
  - Eye/Face: Chemical safety goggles + face shield (for bulk handling)
  - Skin: Nitrile rubber gloves (thickness ≥0.1mm) + impermeable protective clothing
  - Respiratory: N95 dust mask (for powder handling); SCBA (for emergency spills)
  - Other: Anti-static shoes, disposable hairnet/mask (GMP compliance)
- **Hygiene:** Dedicated hand washing station; no food/drinks in the work area; separate storage of work clothes and daily clothes.

## SECTION 9: Physical and Chemical Properties

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Property	Value
Physical State	White to off-white crystalline powder
Odor	Odorless
Melting Point	142 ~ 146°C
Boiling Point	Decomposes before boiling (>200°C)
Flash Point	Non-flammable (no flash point)
Autoignition Temperature	>300°C
Solubility	Freely soluble in methanol; soluble in water/ethanol; slightly soluble in ether
pH Value (1% aqueous solution, 25°C)	5.0 ~ 7.0
Density (25°C, solid)	1.21 g/cm <sup>3</sup>

Property	Value
Vapor Pressure (25°C)	<0.001 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 to Avoid:** High temperature (>25°C), direct sunlight, moisture, contact with strong acids/alkalis/oxidizing agents.
- **Incompatible Materials:** Strong acids (HCl, H<sub>2</sub>SO<sub>4</sub>), strong bases (NaOH, KOH), oxidizing agents (H<sub>2</sub>O<sub>2</sub>, KMnO<sub>4</sub>), heavy metal salts (AgNO<sub>3</sub>, CuSO<sub>4</sub>).
- **Hazardous Decomposition Products:** Nitrogen oxides (NO<sub>x</sub>), carbon monoxide (CO), and organic amines (at >200°C).
- No polymerization under normal conditions.

## SECTION 11: Toxicological Information

### 11.1 Key Toxicological Data

- **Acute Toxicity:**
  - Oral (Rat, LD<sub>50</sub>): 325 mg/kg bw
  - Dermal (Rabbit, LD<sub>50</sub>): 450 mg/kg bw
  - Inhalation (Rat, LC<sub>50</sub>, 4h): 1.2 mg/m<sup>3</sup> (dust)
- **Skin Irritation (Rabbit):** Mild irritation (4h exposure, no erythema/edema)
- **Eye Irritation (Rabbit):** Moderate irritation (24h exposure, reversible conjunctivitis)
- **Sensitization:** No skin/respiratory sensitization (Guinea pig test)
- **Carcinogenicity:** IARC Class 3 (Not classifiable as to its carcinogenicity to humans)
- **Reproductive Toxicity:** Suspected of mild fertility damage (rat test, high dose); no teratogenic effect.
- **Target Organ Toxicity:** Central nervous system (depression, respiratory center inhibition); cardiovascular system (bradycardia, hypotension).

### 11.2 Toxicity Summary

The main toxic effect is central nervous system depression; accidental exposure causes respiratory/cardiovascular depression, which is reversible with opioid antagonists (e.g., naloxone). No chronic toxic effects at occupational exposure levels.

## SECTION 12: Ecological Information

### 12.1 Ecotoxicity

- Fish (Zebrafish, LC<sub>50</sub>, 96h): 2.5 mg/L
- Daphnia (EC<sub>50</sub>, 48h): 1.8 mg/L
- Algae (EC<sub>50</sub>, 72h): 3.2 mg/L
- **Conclusion:** Slightly toxic to aquatic organisms; high toxicity to small invertebrates.

### 12.2-12.7 Ecological Properties

- **Persistence/Degradability:** Not biodegradable (BOD<sub>5</sub>/COD <0.1)
- **Bioaccumulative Potential:** High (log Kow=4.8; bioaccumulation factor (BAF) >1000 in fish)
- **Mobility in Soil:** Low (adsorbs strongly to soil organic matter; no leaching to groundwater)
- **PBT/vPvB:** Classified as PBT (Persistent, Bioaccumulative, Toxic)
- **Other Adverse Effects:** No adverse effects on soil microorganisms; do not discharge into water bodies/soil.

## SECTION 13: Disposal Considerations

### 13.1 Waste Treatment

- **Product Waste:** Classified as **hazardous pharmaceutical waste** and **narcotic drug waste**; dispose of by licensed hazardous waste treatment enterprises (incineration at >800°C with flue gas treatment).
- **Packaging Waste:** Rinse packaging with methanol (3 times); the rinse solution is incinerated with the product waste; the clean packaging is disposed of as pharmaceutical solid waste (or recycled if GMP-compliant).
- **Do not dispose of with household waste or general industrial waste;** do not discharge into sewers/rivers/soil.

## 13.2 Disposal Regulations

Comply with China's **Hazardous Waste Pollution Control Law**, **Narcotic Drug Administration Law**, and EU **WEEE/REACH** 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:** Alfentanil (narcotic drug, solid)
- **Transport Hazard Class:** 6.1 (Toxic substances)
- **Packaging Group:** II
- **Marine Pollutant:** Yes (P)
- **Special Transport Requirements:**
  1. Classified as **national narcotic controlled drug**; transport with **narcotic drug transport license** (issued by drug regulatory department).
  2. Refrigerated transport (2~8°C) with temperature monitoring; use sealed, shockproof, moisture-proof packaging.
  3. Load/unload gently; avoid package damage; store separately from food, feed, and oxidizing agents in the transport vehicle.
  4. The transport vehicle is equipped with fire-fighting equipment and emergency spill treatment materials; no smoking/open fire during transport.
- **International Transport:** Comply with **UN Single Convention on Narcotic Drugs (1961)** and IATA/IMDG regulations.

## 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 (Good Manufacturing Practice) for pharmaceutical raw materials
- **International:**
  - UN Single Convention on Narcotic Drugs (1961) (Schedule I)
  - GHS Rev.9 (hazard classification)
  - EP 10.0 / USP 45 (pharmacopoeial standards)
  - REACH (EU) (registered; not in SVHC Candidate List)
  - TSCA (US) (listed on the TSCA Inventory)

### 15.2 Other Requirements

- Production/sale/use requires a **special license** for narcotic drugs (issued by national drug regulatory department).
- Occupational operation requires professional training and certification; compliance with GMP/GLP guidelines.

## SECTION 16: Other Information

- **MSDS Validity:** This MSDS is valid for 3 years from the revision date (08 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.



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- **Additional Information:** For more technical/formulation data, contact the supplier's technical department (+86-021-50350039 ext. 808).
- **Key Reminder:** This product is a **controlled narcotic drug**; any illegal production/sale/use will be subject to criminal liability in accordance with the law.



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