

## 1. Identification

Product identifier	Fentanyl CII	
Other means of identification		
Catalog number	1269902	
CAS number	437-38-7	
Synonyms	Fentanyl base, fentanyl alkaloid	
Chemical name	N-(1-Phenethyl-4-piperidyl)propionanilide	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	<a href="http://www.usp.org">www.usp.org</a>	
E-mail	<a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	
Emergency phone number	CHEMTRAC within US & Canada	1-800-424-9300
	CHEMTRAC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 2
	Acute toxicity, dermal	Category 2
	Acute toxicity, inhalation	Category 2
	Specific target organ toxicity, single exposure	Category 3 narcotic effects
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		
Signal word	Danger	
Hazard statement	Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled. May cause drowsiness or dizziness.	
Precautionary statement		
Prevention	Wash thoroughly after handling. Do not get in eyes, on skin, or on clothing. Wear protective gloves/protective clothing. Do not breathe dust. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation wear respiratory protection.	
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. Immediately call a poison center/doctor. Take off immediately all contaminated clothing and wash it before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing.	
Storage	Store locked up. Store in a well-ventilated place. Keep container tightly closed.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	

**Hazard(s) not otherwise classified (HNOC)**

None known.

**Supplemental information**

Highly potent pharmacologically active material.

### 3. Composition/information on ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Fentanyl CII	Fentanyl base, fentanyl alkaloid	437-38-7	100

### 4. First-aid measures

#### Inhalation

Remove victim to fresh air and keep at rest in a position comfortable for breathing. Do not use mouth-to-mouth method if the substance is inhaled. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.

#### Skin contact

Take off immediately all contaminated clothing. Wash off with soap and water. Call a physician or poison control center immediately. Wash contaminated clothing before reuse.

#### Eye contact

Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control center immediately.

#### Ingestion

Call a physician or poison control center immediately. Rinse mouth. Do not use mouth-to-mouth method if substance is ingested. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

#### Most important symptoms/effects, acute and delayed

Narcotic effects. Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

#### Indication of immediate medical attention and special treatment needed

Treat symptomatically. Treatment of opioid analgesic overdose may include the following: Do not induce vomiting. Administer activated charcoal as a slurry. Monitor vital signs, pulse oximetry, and cardiac function. Monitor for CNS and respiratory depression. For respiratory depression, administer oxygen and assist ventilation. Protect airway with orotracheal intubation. For coma and respiratory depression, reverse with naloxone. Administer intravenously, intramuscularly, intratracheally, intranasally, or subcutaneously. A continuous infusion might be needed for long-acting opioids. For seizures, treat with intravenous benzodiazepines. If seizures persist, administer propofol or barbiturates. For hypotension, treat with an infusion of isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. Hemodialysis and hemoperfusion are not recommended.

#### General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

#### Suitable extinguishing media

Water. Foam. Dry chemical or CO<sub>2</sub>. Use fire-extinguishing media appropriate for surrounding materials.

#### Unsuitable extinguishing media

None known.

#### Specific hazards arising from the chemical

No unusual fire or explosion hazards noted.

#### Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

#### Fire fighting equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

#### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

#### General fire hazards

No unusual fire or explosion hazards noted.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

### Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

### Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

### Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

### Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### Exposure limit values

##### Industrial Use

##### Material

##### Type

##### Value

Fentanyl CII (CAS 437-38-7)

STEL

2 micrograms/m<sup>3</sup>

TWA

0.7 micrograms/m<sup>3</sup>

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Appropriate engineering controls

No open handling. For laboratory operations, conduct powder handling operations in an isolator or equivalent. Put powder into solution or a tightly capped container prior to removal from containment. Isolator should be equipped with bag out ports or transfer chamber. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

#### Skin protection

##### Hand protection

Wear double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

##### Other

Train employees in proper gowning and degowning practices. Wear disposable laboratory coat and disposable sleeve covers appropriate to the task, two pairs of gloves, and safety glasses with side shields. An anteroom or transition area is recommended for gowning and degowning. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

#### Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

#### Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

### General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

## 9. Physical and chemical properties

### Appearance

Appearance descriptions are general information and not specific to any USP lot.

#### Physical state

Solid.

#### Form

Powder.

<b>Color</b>	White.
<b>Odor</b>	Odorless.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	181.4 - 188.6 °F (83 - 87 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	< 0.0000001 kPa at 25 °C
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Practically insoluble.
<b>Solubility (other)</b>	Alcohol: Freely soluble. Methanol: Freely soluble.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Phenylpiperidine derivative.
<b>Molecular formula</b>	C22H28N2O
<b>Molecular weight</b>	336.47

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Fatal if inhaled. May cause drowsiness and dizziness. Headache. Nausea, vomiting.
<b>Skin contact</b>	Fatal in contact with skin. Based on information from therapeutic use, this material may cause: Narcotic effects.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Fatal if swallowed. Based on information from therapeutic use, this material may cause: Narcotic effects.

**Symptoms related to the physical, chemical, and toxicological characteristics**

Opioids: Respiratory depression. Central nervous system depression. Gastrointestinal disturbances. Mood or mental changes. Pinpoint pupils. Muscle rigidity. Seizures.

**Information on toxicological effects**

**Acute toxicity**

Fatal if inhaled. Fatal in contact with skin. Fatal if swallowed.

**Product**

**Species**

**Test Results**

Fentanyl CII (CAS 437-38-7)

**Oral**

LD50

Mouse

368 mg/kg

Rat

18 mg/kg

**Skin corrosion/irritation**

Knowledge about health hazard is incomplete.

**Serious eye damage/eye irritation**

Knowledge about health hazard is incomplete.

**Respiratory or skin sensitization**

**Respiratory sensitization**

Knowledge about health hazard is incomplete.

**Skin sensitization**

Knowledge about health hazard is incomplete.

**Germ cell mutagenicity**

**Mutagenicity**

Ames test

Result: Negative.

Micronucleus assay

Result: Negative.

Mouse lymphoma assay

Result: Negative.

**Carcinogenicity**

Knowledge about carcinogenicity is incomplete.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity**

Based on available data, the classification criteria are not met. Maternal use of opioids during pregnancy may cause physical dependence in the fetus leading to respiratory difficulties and withdrawal symptoms (dehydration, irritability, tremors, excessive crying, diarrhea) in the newborn.

**Reproductivity**

10 - 500 microgram/kg Developmental study

Result: No teratogenic or embryotoxic effects seen.

Species: Rat

500 microgram/kg Reproduction study

Result: No adverse reproductive effects.

Species: Rat

**Specific target organ toxicity - single exposure**

May cause drowsiness and dizziness.

**Specific target organ toxicity - repeated exposure**

Knowledge about health hazard is incomplete.

**Aspiration hazard**

Based on available data, the classification criteria are not met.

**Further information**

Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

**12. Ecological information**

**Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

**Persistence and degradability**

No data is available on the degradability of this substance.

**Bioaccumulative potential**

No data available.

**Mobility in soil**

No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

<b>Disposal instructions</b>	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

**DOT**

<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Fentanyl)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	II

**IATA**

<b>UN number</b>	UN2811
<b>UN proper shipping name</b>	Toxic solid, organic, n.o.s. (Fentanyl)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1
<b>Subsidiary risk</b>	-
<b>Packing group</b>	II
<b>Other information</b>	
<b>Passenger and cargo aircraft</b>	Allowed with restrictions.
<b>Cargo aircraft only</b>	Allowed with restrictions.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.

**DOT; IATA**



**General information**

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)****SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical**

**Classified hazard categories** Acute toxicity (any route of exposure)  
Specific target organ toxicity (single or repeated exposure)

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)**

Not regulated.

**Drug Enforcement Administration (DEA) (21 CFR 1308.11-15)**

Schedule II - 9801

**US state regulations****California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

**Issue date** 02-28-2019

**Revision date** 02-28-2019

**Version #** 02

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