

# Safety Data Sheet



## 1. Identification

<b>Product Identifier</b>	Sufentanil Citrate
<b>Other means of identification</b>	
<b>Internal item number</b>	82393-0121
<b>CAS number</b>	60561-17-3
<b>Chemical name</b>	Propanamide, N-[4-(methoxymethyl)-1-[2-(thienyl)ethyl]-4-piperidinyl]-N-phenyl, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)
<b>Relevant use and restrictions:</b>	No further information available.
<b>Application of substance:</b>	Active pharmaceutical ingredient.
<b>Manufacturer/Supplier information</b>	
<b>Company name</b>	Pharma Source Direct
<b>Address</b>	8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112
<b>Website</b>	www.pharmasd.com
<b>Emergency phone number</b>	Infotrac: 1-800-535-5053

## 2. Hazard(s) Identification

<b>Physical hazards</b>	Not classified	
<b>Health hazards</b>	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
<b>Environmental hazards</b>	Not classified	
<b>OSHA defined hazards</b>	Not classified	
<b>Label elements</b>		

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**Signal word**

Danger

**Hazard statement**

Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled. May cause drowsiness or dizziness.

**Precautionary statement**  
**Prevention**

Do not breathe dust/fume. Wash thoroughly after handling. Wear protective gloves/protective clothing. Do not get in eyes, on skin, or on clothing. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation wear respiratory protection.

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<b>Response</b>	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. Immediately call a poison center/doctor.
<b>Storage</b>	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/ international regulations.
<b>Hazards not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	Potent pharmacologically active material.

### 3. Composition/Information on Ingredients

#### Substance

Chemical name	Common name and synonyms	CAS number	%
Sufentanil Citrate		60561-17-3	100

### 4. First-aid Measures

<b>Inhalation</b>	Remove to fresh air. Oxygen or artificial respiration if needed. 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.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Call a physician or poison control center immediately. Take off contaminated clothing and wash before reuse.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth thoroughly. Never give anything by mouth to a person who is unconscious or is having convulsions. 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. Do not use mouth-to-mouth method if substance is ingested. Call a physician or poison control center immediately.
<b>Most important symptoms/effects, acute and delayed</b>	Narcotic effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	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

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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.

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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No unusual fire or explosion hazards noted.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental Release Measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and Storage

<b>Precautions for safe handling</b>	As a general rule, 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
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## Conditions for safe storage, including any incompatibilities

use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure Controls & Personal Protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

### Exposure limit values

#### Industrial Use

Material	Type	Value
Sufentanil Citrate (CAS 60561-17-3)	STEL	0.2 micrograms/m <sup>3</sup>
	TWA	0.07 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, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). 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 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.

##### Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. 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

Pharmacological effects may be seen with occupational exposure. Procedures for any use or quantity should be determined after an appropriate assessment.

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## 9. Physical and Chemical Properties

<b>Appearance</b>	Appearance descriptions are general information and not specific to any lot.
<b>Physical state</b>	Solid.
<b>Form</b>	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>	271.4 - 284 °F (133 - 140 °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 (77 °F (25 °C))
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Soluble.
<b>Solubility (other)</b>	Ethanol: Sparingly soluble. Methanol: Freely soluble. Acetone: Sparingly soluble. Chloroform: Sparingly soluble.
<b>Partition coefficient (n-octanol/water)</b>	3.45
<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>	C <sub>22</sub> H <sub>30</sub> N <sub>2</sub> O <sub>2</sub> S . C <sub>6</sub> H <sub>8</sub> O <sub>7</sub>
<b>Molecular weight</b>	578.67

## 10. Stability and Reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
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<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>	Contact with incompatible materials.
<b>Incompatible materials</b>	Oxidizing agents.
<b>Hazardous decomposition products</b>	NOx. SOx. 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.
<b>Skin contact</b>	Fatal in contact with skin.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Fatal if swallowed.

**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
Sufentanil Citrate (CAS 60561-17-3)		
<u>Acute</u>		
<b>Dermal</b>		
LD50	Rat	50 – 200 mg/kg
<b>Inhalation</b>		
LC50	Rat	0.05 – 0.5 mg/l
<b>Oral</b>		
LD50	Rat	5 – 50 mg/kg
<b>Skin corrosion/irritation</b>	Knowledge about health hazard is incomplete.	
<b>Serious eye damage/eye irritation</b>	Knowledge about health hazard is incomplete.	
<b>Respiratory or skin sensitization</b>		
<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Skin sensitization</b>	Knowledge about health hazard is incomplete.	
<b>Germ cell mutagenicity</b>	Knowledge about mutagenicity is incomplete.	
<b>Carcinogenicity</b>	Knowledge about carcinogenicity is incomplete.	
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>		
Not listed.		
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)</b>		
Not regulated.		
<b>US. National Toxicology Program (NTP) Report on Carcinogens</b>		
Not listed.		
<b>Reproductive toxicity</b>	Knowledge about health hazard is incomplete. Fetal exposure to opioids may lead to respiratory difficulties and withdrawal symptoms in the newborn.	

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## Reproductivity

<= 100 microgram/kg Reproductivity study  
Result: No increase in birth defects in the offspring.  
Species: Rat

## Specific target organ toxicity - single exposure

Narcotic effects.

## 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

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 product.

### Bioaccumulative potential

#### Octanol/water partition coefficient log K<sub>ow</sub>

3.45

### 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

### Disposal instructions

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.

### Local disposal regulations

Dispose in accordance with all applicable regulations.

### Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

### Waste from residues / unused products

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).

### Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport Information

### DOT

#### UN number

UN2811

#### UN proper shipping name

Toxic solid, organic, n.o.s. (Sufentanil Citrate)



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## Transport hazard class(es)

**Class** 6.1

**Subsidiary risk** -

**Packing group** II

**Packaging Exceptions** E4

## IATA

**UN number** UN2811

**UN proper shipping name** Toxic solid, organic, n.o.s. (Sufentanil Citrate)

## Transport hazard class(es)

**Class** 6.1

**Subsidiary risk** -

**Packing group** II

## Other information

**Passenger and cargo aircraft** Allowed with restrictions.

**Cargo aircraft only** Allowed with restrictions.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

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 1910.1001-1053)

Not regulated.



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## Superfund Amendments and Reauthorization Act of 1986 (SARA)

### SARA 302 Extremely hazardous substance

Not listed.

### SARA 311/312 Hazardous chemical

Yes

#### 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 - 9740

## US state regulations

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)	Yes
Canada	Domestic Substances List (DSL)	Yes
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	No
Phillipines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
Unites 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).

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## 16. Other Information

### Disclaimer

The information in this SDS has been compiled from sources considered dependable, but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product in regards to handling, storage, and/or disposal.

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