

Safety Data Sheet



1. Identification

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

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

Inhalation	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.
Skin contact	Immediately flush skin with plenty of water. Call a physician or poison control center immediately. Take off contaminated clothing and wash before reuse.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	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.
Most important symptoms/effects, acute and delayed	Narcotic effects. 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

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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.

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 ₂ . 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, 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 ³
	TWA	0.07 micrograms/m ³

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

Appearance	Appearance descriptions are general information and not specific to any lot.
Physical state	Solid.
Form	Powder.
Color	White.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	271.4 - 284 °F (133 - 140 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa (77 °F (25 °C))
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble.
Solubility (other)	Ethanol: Sparingly soluble. Methanol: Freely soluble. Acetone: Sparingly soluble. Chloroform: Sparingly soluble.
Partition coefficient (n-octanol/water)	3.45
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Phenylpiperidine derivative.
Molecular formula	C ₂₂ H ₃₀ N ₂ O ₂ S . C ₆ H ₈ O ₇
Molecular weight	578.67

10. Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
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Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Oxidizing agents.
Hazardous decomposition products	NO _x . SO _x . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological Information

Information on likely routes of exposure

Inhalation	Fatal if inhaled. May cause drowsiness and dizziness.
Skin contact	Fatal in contact with skin.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	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)		
Acute		
Dermal		
LD50	Rat	50 – 200 mg/kg
Inhalation		
LC50	Rat	0.05 – 0.5 mg/l
Oral		
LD50	Rat	5 – 50 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	Knowledge about mutagenicity is incomplete.	
Carcinogenicity	Knowledge about carcinogenicity is incomplete.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
Not listed.		
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not regulated.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	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 Kow	
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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