



From: Mallinckrodt Inc.
675 McDonnell Blvd.
St. Louis, MO 63042



24 Hour Emergency Telephone: 314-654-1600
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

SUFENTANIL CITRATE

1. Product Identification

Synonyms: Propionanilide, N-[4-(methoxymethyl)-1-[2-(2-thienyl)ethyl]-4-piperidyl]-N-phenyl-, citrate; Sufentanil Citrate ARS - (FOR R&D USE ONLY)

CAS No: 60561-17-3

Molecular Weight: 578.40

Chemical Formula: C₂₇H₃₁N₃O₃S

Product Codes: 0672, 0801

2. Composition/Information on Ingredients

Ingredient	CAS No.	Percent	Hazardous
Sufentanil citrate	60561-17-3	100%	Yes

3. Hazards Identification

Emergency Overview

DANGER! MAY BE FATAL IF SWALLOWED, INHALED OR ABSORBED THROUGH SKIN. POTENT NARCOTIC.

Potential Health Effects

Described as being 2000 to 4000 times as potent as morphine, the human health effects associated with occupational exposure to Sufentanil are not well documented.

Inhalation:

Narcotic. Can irritate the respiratory passages and cause sneezing or coughing but will also have an anesthetic effect. Inhalation of appreciable quantities may produce lung edema, dizziness, and respiratory difficulties, see also Ingestion, below.

Ingestion:

Toxic! Narcotic. Minimum Lethal Dosage of related compound Fentanyl is 250 ug.

In addition to its analgesic action, morphine may cause gastric disturbance with nausea, vomiting and constipation. Large amounts may cause central nervous system depression, respiratory or cardiac collapse, coma and death.

Skin Contact:

May be absorbed through the skin; toxic effects expected to follow any skin contact.

Eye Contact:

Mild irritant but will also have a strong narcotic effect (pupil constriction) and the eye may serve as an absorption route to the body in general.

Chronic Exposure:

Caution, may be habit forming.

Aggravation of Pre-existing Conditions:

No information found.

4. First Aid Measures

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

Ingestion:

Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person.

Skin Contact:

Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Call a physician, immediately. Wash clothing before reuse.

Eye Contact:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Get medical attention immediately.

Note to Physician:

The principal sign of serious overdose to sufentanyl include stupor and respiratory depression. Treatment for these effects due to fentanyl is the same as for overdose by other opioids: airway maintenance, ventilation support, and administration of a narcotic antagonist such as naloxone (Narcan®) beginning with 0.4 to 2 mg intravenously and repeating every three minutes as clinically indicated. Intramuscular or subcutaneous administration may be necessary if the intravenous route is not available.

5. Fire Fighting Measures

Fire:

As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source.

Explosion:

Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Fire Extinguishing Media:

Water spray, dry chemical, alcohol foam, or carbon dioxide.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7).

6. Accidental Release Measures

Ventilate area of leak or spill. Remove all sources of ignition. Wear appropriate personal protective equipment as specified in Section 8, and follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7). Isolate hazard area. Keep unnecessary and unprotected personnel from entering. All clean-up operations should be witnessed by more than one individual.

Spills: Carefully sweep up material into an appropriate container and save for reclamation or disposal. Use non-sparking tools and equipment. Do not flush to sewer! The amount of material collected should be assessed and documented.

7. Handling and Storage

Store in a tightly sealed light impervious metal container in a cool dry ventilated area. CONTROLLED SUBSTANCE. Location of storage area must comply with all Drug Enforcement Agency regulations. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

Sufentanyl has potent pharmacological activity and is classified as an OEB-3* material. Handling practices for OEB-3 substances are described below:

Laboratory

- * Wear appropriate gloves, lab coat, and safety glasses. Use good lab practices.
- * A designated area is required for handling compounds.
- * Work surfaces are to be cleaned daily. If lab bench absorbent paper is used, it is to be changed at least daily.
- * High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.
- * Develop cleaning procedures and techniques that limit potential exposure.
- * Powders Handling:

To prevent contamination and overexposure, no open handling of powder should be allowed. Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system. In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used. Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs. An air-purifying respirator (P95 or other type providing a higher level of protection) should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.). Powder should be put into solution or a closed or covered container after handling. If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.
- * Solutions Handling:
 - Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolization. If the procedures have a potential for aerosolization, an air-purifying respirator (P95 or other type providing a higher level of protection) is to be worn by all personnel in the immediate area.
 - Solutions used for procedures where aerosolization may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation. In situations where this is not feasible (may include animal dosing), an air-purifying respirator (P95 or other type providing a higher level of protection) is to be worn by all personnel in the immediate area.
 - If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.
 - Ensure gloves are protective against solvents in use.

Pilot Plant and Production

- * Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Use good manufacturing practices (i.e., cGMPs).
- * Protective garment (coveralls, Tyvek, lab coat) is not to be worn outside the work area.
- * Clean/dirty/decontamination areas are to be established.
- * Negative/positive air pressure relationships and buffer zones required (i.e., ante-room/degowning room/airlock).
- * Area access is to be restricted.
- * High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.
- * Develop cleaning procedures and techniques that limit potential exposure.
- * Powders Handling
 - Emphasis is to be placed on closed material transfer systems and process containment, with no open

handling of powders. Use enclosures and containment measures to reduce potential exposures.
- Use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR) until processes have been monitored to show that respiratory protection is not required.

*** Solutions Handling**

- Enclose systems where possible. Processing tanks are to be kept covered. Process samples should be taken from sample ports if feasible.
- Wear a P95 Dust/Mist respirator or a respirator supplying a higher level of protection until processes have been monitored to show that respiratory protection is not required.
- Ensure gloves are protective against solvents in use.

*OEB - Mallinckrodt's Occupational Exposure Band: The classification of a compound or pharmaceutical ingredient into one of four ordinal categories of increasing potency and toxicity. This rating assigns a set of pre-determined handling and containment practices to a compound until a quantitative OEL is established.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

Sufentanil:

Occupational Exposure Guideline (OEG): 0.07×g/m μ , as 8-hour time-weighted average

STEL: 0.2×g/m μ , as 15-minute average, Notation: Skin.

Ventilation System:

To prevent contamination and overexposure, no open handling of powder should be allowed. Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system. In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used. Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs. See Section 7 for additional information on proper handling and venting requirements for potent compounds.

Personal Respirator (NIOSH Approved)

An air-purifying respirator (P95 or other type providing a higher level of protection) should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).

If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use. See Section 7 for additional information on proper handling and respirator recommendations for potent compounds.

Skin Protection:

Wear protective gloves and clean body-covering clothing.

Eye Protection:

Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.

Other Control Measures:

See Section 7 for additional information on occupational control measures appropriate for OEB-3 potent compounds.

9. Physical and Chemical Properties

Appearance:

White granules or powder.

Odor:

Odorless.

Solubility:

Soluble in water.

Boiling Point:

No information found.

Melting Point:

136.3°C (277°F)

Vapor Density (Air=1):

No information found.

Density:

No information found.

pH:

No information found.

% Volatiles by volume @ 21°C (70°F):

No information found.

Vapor Pressure (mm Hg):

No information found.

Evaporation Rate (BuAc=1):

No information found.

10. Stability and Reactivity

Stability:

Discolors on exposure to light.

Hazardous Decomposition Products:

Burning may produce carbon monoxide, carbon dioxide, nitrogen oxides. Decomposes above 80°C

Hazardous Polymerization:

Will not occur.

Incompatibilities:

No information found.

Conditions to Avoid:

No information found.

11. Toxicological Information

Sufentanil: intravenous mouse LD50: 18.7 mg/kg.

Cancer Lists**Ingredient**

Sufentanil citrate (60561-17-3)

---NTP Carcinogen---

Known	Anticipated	IARC Category
No	No	None

12. Ecological Information

Environmental Fate:

Sufentanil will not volatilize from soil, from water or bioconcentrate in aquatic organisms. An estimated Koc range of 406 to 1,790 suggests that sufentanil will have medium to low mobility in soil, and will adsorb to sediment. Based on measured water solubilities at 35 deg C of 3,930 mg/L at pH 5.31 and 3.3 mg/L at pH 7.98, soil adsorption, (and adsorption to sediment), may depend on the pH of the environment with higher mobility in soil, (and with higher adsorption to sediment), occurring under cationic conditions. Sufentanil contains an amide group and may be susceptible to slow environmental chemical hydrolysis.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7).

Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Domestic (Land, D.O.T.)**Proper Shipping Name:**

TOXIC SOLID, ORGANIC, N.O.S. (Propanamide, N-[4-(methoxymethyl)-1-[2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenyl-, 2-hydroxy-1,2,3-

propanetricarboxylate)
Hazard Class: 6.1
UN/NA: UN2811 **Packing Group:** II
Information reported for product/size: all sizes

15. Regulatory Information

Chemical Inventory Status

Ingredient	TSCA	EC	Japan	Australia	Korea	---Canada---		
						DSL	NDSL	Phil.
Sufentanil citrate (60561-17-3)	Exempt	Yes	No	Yes	No	No	No	No

Federal, State & International Regulations

Ingredient	---SARA 302---		-----SARA 313-----		CERCLA	261.33	-RCRA-	-TSCA-
	RQ	TPQ	List	Chemical Catg.				
Sufentanil citrate (60561-17-3)	No	No	No	No	No	No	No	8(d)

Chemical Weapons Convention: No **TSCA 12(b):** No **CDTA:** No
SARA 311/312: Acute: Yes Chronic: Yes Fire: No Pressure: No Reactivity: No (Pure / Solid)
Australian Hazchem Code: 2XE **Australian Poison Schedule:** S8
WHMIS: This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings:

Health: 4 Flammability: 1 Reactivity: 1

Label Hazard Warning:

DANGER! MAY BE FATAL IF SWALLOWED, INHALED OR ABSORBED THROUGH SKIN. POTENT NARCOTIC.

Label Precautions:

Do not breathe dust.
Do not get in eyes, on skin, or on clothing.
Keep container closed.
Use only with adequate ventilation.
Wash thoroughly after handling.
Wear gloves and protective clothing.

Label First Aid:

In all cases call a physician immediately. If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes.

Product Use:

Medication: Analgesic agent

Revision Information:

MSDS Section(s) changed since last revision of document include: 3, 4, 5, 6, 7, 8, 13, 14, 15, 16.

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Prepared By: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)