

SAFETY DATA SHEET**1. Identification**

Product Identifier: Sufentanil Citrate Injection, USP

Synonyms: Propanamide, N-[4-(methoxymethyl)-1-[2-(thienyl)ethyl]-4-piperidinyl]-N-phenyl, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)

National Drug Code (NDC): 17478-050-01
17478-050-02
17478-050-05

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
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Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

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Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s):

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash hands thoroughly after handling.

P314 Get medical advice/attention if you feel unwell.

P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
+
P351 present and easy to do. Continue rinsing.
+
P338

P337 If eye irritation persists: Get medical advice/attention.
+
P313

Hazards Not Otherwise Classified: Not classifiable.

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Supplementary Information:

While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Sufentanil Citrate	60561-17-3	Propanamide, N-[4-(methoxymethyl)-1-[2-(thienyl)ethyl]-4-piperidinyl]-N-phenyl, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)	C ₂₈ H ₃₈ N ₂ O ₉ S	578.68	0.005 %

*The solution has pH range of 3.5 – 6.0.

4. First Aid Measures

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

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Signs and Symptoms: None anticipated from normal handling of this product. In clinical use, the most common adverse reactions are respiratory depression, skeletal muscle rigidity, and drowsiness. Less frequently, bradycardia, hypotension/hypertension, and chest wall rigidity may occur. Other adverse effects (occurring in <1% of patients) may include tachycardia, arrhythmia, nausea, vomiting, apnea, bronchospasm, itching and chills. Overdose results in an exaggeration of the pharmacological effects described above.

Medical Conditions Aggravated by Exposure:

Not determined.

Notes to Physician:

The principal signs of serious overdose to sufentanil include stupor and respiratory depression.

5. Firefighting Measures

Flammability:

None anticipated for this aqueous product.

Suitable Extinguishing Media:

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

Unsuitable Extinguishing Media:

Not determined.

Special Fire Fighting Procedures:

No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:

Not determined.

Other Specific Hazards:

Not determined.

Special Protective Equipment Precautions for Firefighters:

No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

6. Accidental Release Measures

Personal Precautions:

Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment:

For personal protection see section 8.

Methods for Cleaning Up:

Ventilate area of leak or spill. Remove all sources of ignition. Isolate hazard area. Keep unnecessary and unprotected personnel from entering. More than one individual should witness all clean-up operations. Carefully sweep up material into an appropriate container and save for disposal. Use non-sparking tools and equipment. Do not flush to sewer! The amount of material collected should be assessed and documented.

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Environmental Precautions: No data available.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: No special handling required for hazard control under conditions of normal product use. In the US, Sufentanil Citrate Injection is a Schedule II controlled drug substance. Appropriate training and procedures may be required when handling a controlled substance.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Sufentanil Citrate	OEG: 0.7 µg/m ³ , 8 hour TWA STEG: 2 µg/m ³ , 15 minute TWA, Notation: Skin

Engineering Controls: Engineering controls are normally not needed during the normal use of this product.

Respiratory Protection: Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Eyes Protection: Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

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Hand Protection:	Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	3.5 – 6.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	0.9961 g/mL at 25°C.
Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under standard use and storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	No data available.
Incompatible Materials:	Oxidizing agents.
Hazardous Decomposition Products:	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and sulfur oxides (SOx).

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Hazardous Polymerization: Not anticipated to occur with this product.

11. Toxicological Information

Information on the Likely Routes of Exposure:

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; large dose inhalation may result in respiratory difficulties.

Ingestion: Toxic! Narcotic. Large amounts may cause central nervous system depression, respiratory or cardiac collapse, coma and death. Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person.

Skin Contact: Absorption through skin may occur.

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.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity:

Compound	Percent	Species	Route	Test Type	Dose
Sufentanil Citrate	100%	Rat	Intravenous	LD ₅₀	17.9 mg/kg
Sufentanil Citrate	100%	Mouse	Intravenous	LD ₅₀	18.7 mg/kg
Sufentanil Citrate	100%	Guinea Pig	Intravenous	LD ₅₀	11.8,13.0 mg/kg
Sufentanil Citrate	100%	Dog	Intravenous	LD ₅₀	14.1,10.1,19.5 mg/kg

LD₅₀: Dosage that produces 50% mortality.

Occupational Exposure Potential: Information on the absorption of this product via inhalation or skin contact is not available. By analogy to fentanyl, sufentanil may have some potential for dermal absorption. Avoid liquid aerosol generation and skin contact.

Acute Toxicity – Dermal: No data available.

Acute Toxicity – Inhalation: No data available.

Corrosivity: No data available.

Dermal Irritation: None anticipated from normal handling of this product.

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Eye Irritation:	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.
Dermal or Respiratory Sensitization:	None anticipated from normal handling of this product.
Toxicokinetics/Metabolism:	No data available.
Specific Target Organ Toxicity – Single Exposure:	No data available.
Specific Target Organ Toxicity – Repeat Exposure:	Based on clinical use, possible target organs include the nervous system, respiratory system, and cardiovascular system.
Reproductive Effects:	<p>None anticipated from normal handling of this product. Reproduction studies performed in rats and rabbits given doses of up to 2.5 times the upper human intravenous dose for a period of 10 to over 30 days revealed high maternal mortality rates due to decreased food consumption and anoxia, which preclude any meaningful interpretation of the results.</p> <p>Sufentanil has been shown to have an embryocidal effect in rats and rabbits when given in doses 2.5 times the upper human intravenous dose for a period of 10 days to over 30 days. These effects may be due to maternal toxicity (decreased food consumption with increased mortality) following prolonged administration of the drug.</p>
Carcinogenicity:	No long-term animal studies of Sufentanil have been performed to evaluate carcinogenic potential.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
Mutagenicity:	A micronucleus test in female rats indicated that single intravenous doses of Sufentanil as high as 80 mcg/kg produced no structural chromosome mutations. The Ames Salmonella typhimurium metabolic activating test also produced no mutagenic activity.
Aspiration Hazard:	None anticipated from normal handling of this product.

12. **Ecological Information**

Ecotoxicity

Aquatic:	Sufentanil will not volatilize from soil, from water or bioconcentrate in aquatic organisms.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	An estimated Koc range of 406 to 1,790 suggests that sufentanil will have medium to low mobility 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.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. **Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

14. **Transport Information**

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class(es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.

15. **Regulatory Information**

US Federal Regulations:

Toxic Substance Control Act (TSCA):	Exempt.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.

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SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

California Proposition 65: Not listed.

16. Other Information

Not made with natural rubber latex.

Revision Date: 04/27/2015

Revision Number: 1

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