

SAFETY DATA SHEET

Preparation Date: No data available

Revision Date: Not Applicable

Revision Number: Not Applicable

1. IDENTIFICATION

Product identifier

Product code: F1147
Product Name: FENTANYL CITRATE (CII), USP

Other means of identification

Synonyms: Phentanyl citrate
 Fentanyl citrate
 Fentaz
 Leptanal
 N-(1-Phenethyl-4-piperidinyl)propionanilide dihydrogen citrate
 N-(1-Phenethyl-4-piperidyl)propionanilide citrate
 N-(1-Phenethyl-4-piperidyl)propionanilide dihydrogen citrate
 Sublimaze

CAS #: 990-73-8
RTECS # UE5600000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: No information available.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral	Category 2
Acute toxicity - Dermal	Category 2
Acute toxicity - Inhalation (Dusts/Mists)	Category 2
Skin sensitization	Category 1
Specific target organ toxicity (single exposure)	Category 3

Label elements

Danger

Hazard statements

Fatal if swallowed
Fatal in contact with skin
Fatal if inhaled
May cause drowsiness or dizziness
May cause an allergic skin reaction



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

May be habit forming

Precautionary Statements - Prevention

Do not eat, drink or smoke when using this product
Wear respiratory protection
Wear protective gloves/protective clothing/eye protection/face protection
Do not get in eyes, on skin, or on clothing
Do not breathe dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Wash face, hands and any exposed skin thoroughly after handling
Contaminated work clothing should not be allowed out of the workplace

Precautionary Statements - Response

Specific treatment (see .? on this label)
Specific measures (see .? on this label)
Specific treatment is urgent (see .? on this label)
Specific treatment (see .? on this label)
Immediately call a POISON CENTER or doctor/physician
IF ON SKIN: Gently wash with plenty of soap and water
Remove/Take off immediately all contaminated clothing
Wash contaminated clothing before reuse
If skin irritation or rash occurs: Get medical advice/attention
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician. Call a POISON CENTER or doctor/physician if you feel unwell.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
Rinse mouth

Precautionary Statements - Storage

Store locked up
Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %	Trade Secret
Fentanyl Citrate 990-73-8	990-73-8	100	*

4. FIRST AID MEASURES**First aid measures****General Advice:**

Poison information centers in each State capital city can provide additional assistance for scheduled poisons (13 1126).

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact:

Flush eye with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

Inhalation:

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Fatal if swallowed. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Immediate medical attention is required. Call a physician or Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed**Symptoms**

Fatal if swallowed, in contact with skin or if inhaled. May cause drowsiness or dizziness.. May cause allergic skin reaction. May be habit forming. May cause eye irritation. May cause skin irritation.

Indication of any immediate medical attention and special treatment needed**Notes to Physician:**

Treat symptomatically

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

5. FIRE-FIGHTING MEASURES**Extinguishing Media****Suitable Extinguishing Media:**

Dry chemical. Carbon dioxide (CO2). Water spray. Foam.

Unsuitable Extinguishing Media:

No information available.

Specific hazards arising from the chemical**Hazardous Combustion Products:**

Carbon oxides. Nitrogen oxides

Specific hazards:May be combustible at high temperatures
When heated to decomposition it emits toxic fumes**Special Protective Actions for Firefighters**

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Evacuate personnel to safe areas. Avoid breathing dust. Avoid dust formation. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Remove all sources of ignition. All equipment used when handling the product must be grounded.

Environmental precautions Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Use appropriate tools to put the spilled solid in a suitable waste disposal container. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. All equipment used when handling the product must be grounded. Remove all sources of ignition. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not breathe vapours/dust. Do not ingest. Do not smoke. Keep away from heat and sources of ignition. Use only in well-ventilated areas. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Sensitive to light. Store in light-resistant containers. Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Keep away from heat and sources of ignition. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents. Acids.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Fentanyl Citrate 990-73-8	None	None	None	None

Canada

Components	Alberta	British Columbia	Ontario	Quebec
Fentanyl Citrate 990-73-8	None	None	None	None

Australia and Mexico

Components	Australia	Mexico
Fentanyl Citrate 990-73-8	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

- Eye protection:** Goggles or Safety glasses with side-shields
- Skin and body protection:** Chemical resistant protective suit. Gloves. Boots.
- Respiratory protection:** Wear respirator with dust filter. Be sure to use an approved/certified respirator or equivalent..
- Hygiene measures:** Avoid contact with skin, eyes and clothing. When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

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Physical state: Solid.	Appearance: Powder.	Color: White.
Odor: Odorless.	Taste No information available	Molecular/Formula weight: 528.59
Formula: C22H28N2O.C6H8O7	Flammability: No information available	Flash point (°C): No data available
Flashpoint (°C/°F): No information available.	Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available
Lower Explosion Limit (%): No information available	Upper Explosion Limit (%): No information available	pH: No information available
Melting point/range(°C/°F): 147-152°C/ 296.6-305.6°F	Boiling point/range(°C/°F): No information available	Bulk density: No information available
Decomposition temperature(°C/°F): No information available	Density (g/cm3): No information available	Specific gravity: No information available
Vapor pressure @ 20°C (kPa): No information available	Evaporation rate: No information available	Vapor density: No information available
VOC content (g/L): No information available	Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): 8.4
Viscosity: No information available	Miscibility: No information available	Solubility: Soluble in cold water Soluble in Methanol Solubility in water: 1g/ 40 ml water Slightly soluble in chloroform Slightly soluble in isopropanol Slightly soluble in Acetone Slightly soluble in Ethanol Very slightly soluble in diethyl ether

10. STABILITY AND REACTIVITY

Reactivity

Reactive with oxidizing agents
Reactive with acids
May discolor on exposure to light

Chemical stability

Stability:

Sensitive to light. Exposure to light accelerates decomposition. Stable under recommended storage conditions.

Possibility of Hazardous Reactions:

Hazardous polymerization does not occur

Conditions to avoid:

Heat. Ignition sources. Incompatible materials. Exposure to light.

Incompatible Materials:

Oxidizing agents. Acids.

Hazardous decomposition products:

Carbon oxides. Nitrogen oxides (NO_x).

Other Information

Corrosivity:

Non-corrosive in presence of glass.

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Eyes. Inhalation. Ingestion.

Acute Toxicity

Component Information

Fentanyl Citrate - 990-73-8

LD50/oral/rat = 18 mg/kg Oral LD50 Rat

LD50/oral/mouse = 368 mg/kg

LD50/dermal/rat = No information available

LD50/dermal/rabbit = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = 18mg/kg

LD50/oral/mouse =

Value - Acute Tox Oral = 368mg/kg

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat

VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available

VALUE-Gas = No information available

VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available

VALUE - Gas = No information available

VALUE - Dust/Mist = No information available

Symptoms

Skin Contact:

Fatal if absorbed through skin. May cause skin irritation. It may be absorbed through the skin.

Eye Contact:

Mild eye irritation. It may have a strong narcotic effect (pupil contraction) and the eyes may serve as an absorption route to the body in general.

Inhalation Fatal if inhaled. Narcotic. It can cause respiratory tract irritation and sneezing or coughing.
It may also have an anesthetic effect. Inhalation of large amounts may produce lung edema, respiratory difficulties, and affect behavior/central nervous system (affects similar to ingestion)..

Ingestion Toxic! Narcotic. Fatal if swallowed. It may cause gastric disturbances such as stomach pain, upset stomach, nausea, vomiting, and constipation. Ingestion of large amounts may affect behavior/central nervous system/peripheral nervous system (central nervous system depression or excitation - general anesthetic, headache, restlessness, skeletal and thoracic muscle rigidity, euphoria, somnolence, convulsions, lightheadedness, drowsiness, fainting, dizziness; flaccid paralysis), respiration(respiratory depressant), eyes (miosis (pupil contraction), blurred vision)and cardiovascular system (hypotension, hypertension, bradycardia, circulatory depression, cardiac arrest). When ingested with a tranquilizer, the following adverse reactions may occur: increased risk of cardiovascular depression chills and/or shivering, restlessness, hallucinatory episodes, mental depression.

Aspiration hazard No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Ingestion: May be habit forming upon prolonged or repeated ingestion
Skin and Inhalation: Prolonged or repeated exposure may cause allergic reactions with skin rashes, itching, coughs, stuffy nose, asthma.

Sensitization: No information available

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic

Components	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Fentanyl Citrate	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure No information available
STOT - repeated exposure No information available
Target Organs: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available
Bioaccumulative potential: No information available
Mobility: No information available

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Fentanyl Citrate	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk:
Packing Group: II
ERG No: 154
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Symbol(s): G

TDG (Canada)

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Description: No information available

ADR

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Packing Group: II
Subsidiary Risk: No information available
Classification Code: No information available
Description: No information available
CEFIC Tremcard No: No information available

IMO / IMDG

UN-No: UN2811

Product code: F1147

Product name: FENTANYL CITRATE
(CII), USP

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14. TRANSPORT INFORMATION

Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Description: No information available
IMDG Page: No information available
Marine Pollutant: No information available
EMS: F-A
MFAG: No information available
Maximum Quantity: No information available

RID

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Classification Code: No information available
Description: No information available

ICAO

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Description: No information available

IATA

UN-No: UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
ERG Code: 6L
Description: No information available

15. REGULATORY INFORMATION

International Inventories

Components	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Fentanyl Citrate</i>	Not Listed	Not present	Not present	Not present	Not present	Present	Present 213-588-0

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Fentanyl Citrate	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting <i>de minimis</i>
<i>Fentanyl Citrate</i>	None	None	None	None	None

U.S. TSCA

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
<i>Fentanyl Citrate</i>	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

D1A Very toxic materials

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	Canada (DSL)	Canada (NDSL)
<i>Fentanyl Citrate</i>	Not Listed	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
<i>Fentanyl Citrate</i>	Not listed	Not listed

EU Classification

R-phrase(s)

R43 - May cause sensitization by skin contact.

R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

S -phrase(s)

S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

Components	Classification	Concentration Limits:	Safety Phrases
<i>Fentanyl Citrate</i>		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

T+ - Very toxic.



16. OTHER INFORMATION

Revision Date: Not Applicable
Prepared by: Sonia Owen

Disclaimer: All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet