

SAFETY DATA SHEET

Preparation Date: 09/03/2019

Revision date 09/03/2019

Revision Number: G1

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: Tom Tyner (USA - West Coast)
Contact Person: Ibad Tirmiz (USA - East Coast)

2. HAZARDS IDENTIFICATION

Classification

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

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

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



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

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

Precautionary Statements - Response

IF ON SKIN: Gently wash with plenty of soap and water
Immediately call a POISON CENTER or physician
Take off immediately all contaminated clothing
Wash contaminated clothing before reuse
If skin irritation or rash occurs: Get medical attention
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or physician.
Call a POISON CENTER or physician if you feel unwell.
IF SWALLOWED: Immediately call a POISON CENTER or 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 and container to an approved waste disposal plant in accordance with local, regional, national and international regulations as applicable

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight-%
Fentanyl Citrate	990-73-8	100

4. FIRST AID MEASURES

First aid measures

- General Advice:** National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222. First aider needs to protect himself. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
- Skin Contact:** Wash off immediately with soap and plenty of water. Remove all contaminated clothes and shoes. Continue flushing with plenty of water for at least 15 minutes. Immediate medical attention is required. Call a physician or poison control center immediately. Fatal in contact with skin.
- Eye Contact:** Flush eyes 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. **WARNING!** It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.
- 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**
- May cause drowsiness or dizziness
 - May cause an allergic skin reaction
 - May be habit forming
 - May cause eye irritation
 - May cause skin irritation
 - Sneezing
 - Coughing
 - Upset stomach
 - Nausea
 - Vomiting
 - May cause constipation
 - Headache
 - Somnolence
 - Convulsions
 - Lightheadedness
 - Drowsiness
 - Fainting
 - Blurred vision
 - Hypotension
 - Hypertension

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 (CO ₂). Water spray mist or foam.
Unsuitable Extinguishing Media:	No information available.

Specific hazards arising from the chemical

Hazardous combustion products	Carbon monoxide. Carbon dioxide (CO ₂). Nitrogen oxides (NO _x).
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. Remove all sources of ignition. Keep away from incompatible materials.

Safe Handling Advice:

Wear personal protective equipment. Use only in well-ventilated areas. Avoid contact with skin, eyes and clothing. Do not breathe dust. Do not ingest. Do not smoke. Keep away from heat and sources of ignition. 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. Keep away from heat and sources of ignition. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents
Acids

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Component	CAS No	OSHA	NIOSH	ACGIH	AIHA WEEL
Fentanyl Citrate	990-73-8	None	None	None	None

Canada

Component	CAS No	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Fentanyl Citrate	990-73-8	None	None	None	None

Australia and Mexico

Component	CAS No	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

Physical state: Solid	Appearance: Crystalline powder. Crystals.	Color: White.
Odor: Odorless.	Taste No information available.	Formula C22H28N2O.C6H8O7
Molecular/Formula weight (g/mole): 528.59	Flammability (solid, gas) 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	Melting point/range(°C/°F): 147-152°C/ 296.6-305.6°F	Decomposition temperature(°C/°F): No information available
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH 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 (NOx).

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

The following values are calculated based on chapter 3.1 of the GHS document
Component Information

Fentanyl Citrate	
CAS No	990-73-8

LD50/oral/rat = 18 mg/kg Oral LD50 Rat
LD50/oral/mouse = 368 mg/kg Oral LD50 Mouse
LD50/dermal/rabbit = No information available
LD50/dermal/rat = 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 Toxicity = 18 mg/kg

LD50/oral/mouse =
Value - Acute Tox = 368 mg/kg

LD50/dermal/rabbit
Value - Acute Toxicity = No information available

LD50/dermal/rat
VALUE - Acute Tox = 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:** May cause sensitization by skin contact.
- Mutagenic Effects:** No information available
- Carcinogenic effects:** Not considered carcinogenic.

Component	CAS No	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Fentanyl Citrate	990-73-8	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

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 respiratory system.
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 in soil No information available
Other adverse effects 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

Component	CAS No	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Fentanyl Citrate	990-73-8	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 Class No information available
Packing group: II
Emergency Response Guide Number 154
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions IB8, IP2, IP4, T3, TP33
Symbol(s): [DOT]: (G) - Identifies proper shipping names for which one or more technical names of the hazardous material must be entered in parentheses, in association with the basic description.
Description: UN2811, Toxic solids, organic, n.o.s., 6.1, II

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
Marine Pollutant No Information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, II

ADR

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Packing group II
Subsidiary Risk: No information available
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, II

IMDG

UN-No: UN2811
Proper Shipping Name: Toxic solids, organic, n.o.s.
Hazard Class: 6.1
Subsidiary Risk: No information available
Packing Group: II
Marine Pollutant No information available
EMS: F-A
Special Provisions 274
Description UN2811, Toxic solid, organic, n.o.s. (FENTANYL CITRATE), 6.1, II

RID

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Subsidiary Risk: No information available
Packing group II
Special Provisions 274, 614
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, II

ICAO (air)

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: UN2811, Toxic solid, organic, n.o.s., 6.1, II
Special Provisions A3, A5

IATA

UN Number UN2811
Proper Shipping Name: Toxic solid, organic, n.o.s.
Transport hazard class(es) 6.1
Subsidiary Risk: No information available
Packing group II
Precautionary Statements - Response 6L
Special Provisions No information available
Description: UN2811, Toxic solid, organic, n.o.s., 6.1, II

15. REGULATORY INFORMATION

International Inventories

Component	CAS No	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	China IECSC	Australia (AICS)	EINECS-No.
<i>Fentanyl Citrate</i>	990-73-8	Not Listed	Not present	Not present	Not present	Not listed	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)

Component	CAS No	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Fentanyl Citrate	990-73-8	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Component	CAS No	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 de minimis
<i>Fentanyl Citrate</i>	990-73-8	None	None	None	None	None

U.S. TSCA

Component	CAS No	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Fentanyl Citrate	990-73-8	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information:

The WHMIS 2015 classification of this product has not been validated or reviewed yet.

Canada Hazardous Products Regulation This product has not been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

DSL/NDSL

Component	CAS No	Canada (DSL)	Canada (NDSL)

Fentanyl Citrate	990-73-8	Not Listed	Not Listed
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Component	CAS No	CEPA Schedule I - Toxic Substances
Fentanyl Citrate	990-73-8	Not listed
Component	CAS No	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Fentanyl Citrate	990-73-8	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Component	CAS No	EU GHS - SV - CLP (1272/2008)
Fentanyl Citrate	990-73-8	

EU - CLP (1272/2008)

R-phrase(s)

R43 - May cause sensitization by skin contact

R26/27/28 - Very 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

Component	CAS No	Classification	Concentration Limits:	Safety Phrases
Fentanyl Citrate	990-73-8		No information	

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

Indication of danger:

T+ - Very toxic

T+



16. OTHER INFORMATION

Preparation Date: 09/03/2019
Revision date: 09/03/2019
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