

# Scientific Documentation

## Fentanyl Citrate (CII), USP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp  
769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



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# Specification for Fentanyl Citrate (CII), USP (F1147)

Item Number	F1147
Item	Fentanyl Citrate (CII), USP
CAS Number	990-73-8
Molecular Formula	$C_{22}H_{28}N_2O \cdot C_6H_8O_7$
Molecular Weight	528.60
MDL Number	
Synonyms	N-(1-Phenethyl-4-piperidyl)propionanilide Dihydrogen Citrate

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	102.0 %
LOSS ON DRYING		0.5 %
RESIDUE ON IGNITION		0.5 %
ELEMENTAL IMPURITIES:		
LEAD (Pb)	AS REPORTED	
ARSENIC (As)	AS REPORTED	
SELENIUM (Se)	AS REPORTED	
ORDINARY IMPURITIES		TO PASS TEST
IDENTIFICATION		TO PASS TEST
RETEST DATE		
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS		TO PASS TEST

## *Spectrum Chemical Mfg Corp*

<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	F1147	Lot Number	1MG0062
Item	Fentanyl Citrate (CII), USP	Manufacturer Lot	2102000152
CAS Number	990-73-8	Manufacturer Code	5840
Molecular Formula	C <sub>22</sub> H <sub>28</sub> N <sub>2</sub> O•C <sub>6</sub> H <sub>8</sub> O <sub>7</sub>	Molecular Weight	528.60

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0	102.0 %	99.1 % (M)
LOSS ON DRYING		0.5 %	0.03 (M)
RESIDUE ON IGNITION		0.5 %	0.02 (M)
ELEMENTAL IMPURITIES:			.
LEAD (Pb)	AS REPORTED		<0.05 µg/g
ARSENIC (As)	AS REPORTED		<0.05 µg/g
SELENIUM (Se)	AS REPORTED		<1.0 µg/g
ORDINARY IMPURITIES		TO PASS TEST	PASSES TEST
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			01-FEB-2026
DATE OF MANUFACTURE			01-MAR-2021
APPEARANCE			WHITE CRYSTALLINE POWDER
RESIDUAL SOLVENTS		TO PASS TEST	PASSES TEST
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm (M)
CLASS 2 (solvent) / TOLUENE			<890 ppm (M)
CLASS 3 (solvent) / ETHANOL			<5000 ppm (M)
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm (M)
CLASS 3 (solvent) / TRIETHYLAMINE			<5000 ppm (M)
MONOGRAPH EDITION			(USP-NF) 2023
NOTE:All results reported with (M) are from manufacturer certificate of analysis			.

Certificate of Analysis Results Entered By:

HBERMUDEZ  
Hernan Bermudez  
08-NOV-23 08:19:24

Certificate of Analysis Results Approved By:

SHANSEN  
Selin Hansen  
08-NOV-23 08:52:37

Spectrum Chemical Mfg Corp  
14422 South San Pedro Street  
Gardena 90248 CA



**All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.**

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by SpecGx LLC dba Mallinckrodt at 3600 N. 2nd Street, St. Louis, Missouri (MO) 63147, United States (USA). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# SAFETY DATA SHEET

# spectrum®



Revision date 16-February-2023

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** FENTANYL CITRATE (CII), USP

### Other means of identification

**Product Code(s)** F1147

**UN/ID no** UN2811

**Synonyms** None

### Recommended use of the chemical and restrictions on use

**Recommended use** No information available

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

#### Supplier Address

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

### Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

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

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

**Danger**

#### Hazard statements

Fatal if swallowed, in contact with skin or if inhaled  
May cause drowsiness or dizziness

May cause an allergic skin reaction



**Appearance** Crystalline powder

**Physical state** Solid

**Odor** Odorless

#### 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  
Do not breathe dust/fume/gas/mist/vapors/spray  
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

Specific treatment (see .? on this label)  
Specific treatment is urgent (see .? on this label)  
Specific treatment (see .? on this label)  
IF ON SKIN: Wash with plenty of water and soap  
Immediately call a POISON CENTER or doctor  
Take off immediately all contaminated clothing and wash it before reuse  
If skin irritation or rash occurs: Get medical advice/attention  
Wash contaminated clothing before reuse  
IF INHALED: Remove person to fresh air and keep comfortable for breathing  
Immediately call a POISON CENTER or doctor  
IF SWALLOWED: Immediately call a POISON CENTER or doctor  
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

#### Other information

No information available.

### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%
Fentanyl Citrate	990-73-8	100

### 4. First-aid measures

#### Description of first aid measures

##### General advice

Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.

<b>Inhalation</b>	If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen. IF exposed or concerned: Get medical advice/attention.
<b>Eye contact</b>	Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.
<b>Skin contact</b>	Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. May cause an allergic skin reaction.
<b>Ingestion</b>	Get immediate medical advice/attention. Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person.
<b>Self-protection of the first aider</b>	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Use personal protective equipment as required. See section 8 for more information.

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

**Symptoms** Coughing and/ or wheezing. Difficulty in breathing. Itching. Rashes. Hives.

#### **Indication of any immediate medical attention and special treatment needed**

**Note to physicians** May cause sensitization in susceptible persons. Treat symptomatically.

### **5. Fire-fighting measures**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Large Fire</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Unsuitable extinguishing media</b>	Do not scatter spilled material with high pressure water streams.
<b>Specific hazards arising from the chemical</b>	Product is or contains a sensitizer. May cause sensitization by skin contact.
<b>Hazardous combustion products</b>	Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides (NO <sub>x</sub> ).
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	none.
<b>Sensitivity to static discharge</b>	none.
<b>Special protective equipment for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

### **6. Accidental release measures**

#### **Personal precautions, protective equipment and emergency procedures**

<b>Personal precautions</b>	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid generation of dust. Do not breathe dust. Keep people away from and upwind of spill/leak.
<b>Other information</b>	Refer to protective measures listed in Sections 7 and 8.



## **Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Pick up and transfer to properly labeled containers.

## **7. Handling and storage**

### **Precautions for safe handling**

<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Take off contaminated clothing and wash before reuse. Do not breathe dust. Avoid generation of dust. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product.
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### **Conditions for safe storage, including any incompatibilities**

<b>Storage Conditions</b>	Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Sensitive to light. Store in light-resistant containers.
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## **8. Exposure controls/personal protection**

### **Control parameters**

<b>Exposure Limits</b>	The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.
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### **Appropriate engineering controls**

<b>Engineering controls</b>	Showers Eyewash stations Ventilation systems.
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### **Individual protection measures, such as personal protective equipment**

<b>Eye/face protection</b>	Wear safety glasses with side shields (or goggles).
<b>Hand protection</b>	Wear suitable gloves. Impervious gloves.
<b>Skin and body protection</b>	Impervious clothing. Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.
<b>Respiratory protection</b>	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
<b>General hygiene considerations</b>	Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Do not breathe dust. Take off contaminated clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline powder
Color	White
Odor	Odorless
Odor threshold	No information available

Property	Values	Remarks • Method
pH	no data available	None known
Melting point / freezing point	147 - 152 °C / 296.6 - 305.6 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Soluble in cold water	None known
Solubility(ies)	Solubility in water: 1g/ 40 ml water Soluble in Methanol Slightly soluble in chloroform Slightly soluble in Acetone Slightly soluble in Ethanol Very slightly soluble in diethyl ether	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
<b>Other information</b>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	528.60	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

## 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Excessive heat.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available. Fatal if inhaled. (based on components).
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available. Fatal in contact with skin. (based on components). May cause sensitization by skin contact. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Fatal if swallowed. (based on components).

### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Coughing and/ or wheezing. Difficulty in breathing. Itching. Rashes. Hives.

#### Acute toxicity

#### Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Fentanyl Citrate 990-73-8	= 18 mg/kg ( Rat )	-	-

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	May cause sensitization by skin contact.
<b>Germ cell mutagenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

<b>Ecotoxicity</b>	The environmental impact of this product has not been fully investigated.
<b>Persistence and degradability</b>	No information available.
<b>Bioaccumulation</b>	Inherently biodegradable.
<b>Other adverse effects</b>	No information available.

## 13. Disposal considerations

#### Waste treatment methods

**Waste from residues/unused products**

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging**

Do not reuse empty containers.

## **14. Transport information**

### **DOT**

<b>UN/ID no</b>	UN2811
<b>Proper shipping name</b>	Toxic solids, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Special Provisions</b>	II
<b>Special Provisions</b>	IB8, IP2, IP4, T3, TP33
<b>Marine Pollutant</b>	Severe Marine Pollutant
<b>Description</b>	UN2811, Toxic solids, organic, n.o.s., 6.1, II
<b>Emergency Response Guide Number</b>	154

### **TDG**

<b>UN/ID no.</b>	UN2811
<b>Proper shipping name</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Packing Group</b>	II
<b>Special Provisions</b>	16
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, II

### **MEX**

<b>UN-No</b>	UN2811
<b>Proper Shipping Name</b>	Toxic solid, organic, n.o.s.
<b>Hazard class</b>	6.1
<b>Special Provisions</b>	274
<b>Packing Group</b>	II
<b>Description</b>	UN2811, Toxic solid, organic, n.o.s., 6.1, II

### **ICAO (air)**

<b>UN/ID no.</b>	UN2811
<b>Hazard class</b>	6.1
<b>Packing Group</b>	II
<b>Special Provisions</b>	A3, A5

### **IATA**

<b>UN number</b>	UN2811
<b>Hazard Class</b>	6.1
<b>Packing group</b>	II
<b>Emergency Response Guide Number</b>	6L
<b>Special Provisions</b>	A3, A5

### **IMDG**

<b>UN number</b>	UN2811
<b>Hazard Class</b>	6.1
<b>Packing group</b>	II
<b>EmS-No</b>	F-A, S-A
<b>Special Provisions</b>	274
<b>Marine Pollutant</b>	NP1

### **RID**

<b>UN number</b>	UN2811
<b>Proper shipping name</b>	TOXIC SOLID, ORGANIC, N.O.S.
<b>Hazard Class</b>	6.1
<b>Packing group</b>	II
<b>Classification code</b>	T2
<b>Special Provisions</b>	274, 614
<b>Description</b>	UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, II

**Labels** 6.1

**ADR**

**UN number** UN2811  
**Proper shipping name** Toxic solid, organic, n.o.s.  
**Hazard Class** 6.1  
**Packing group** II  
**Classification code** T2  
**Tunnel restriction code** (D/E)  
**Special Provisions** 274, 614  
**Description** UN2811, Toxic solid, organic, n.o.s., 6.1, II, (D/E)  
**Labels** 6.1

**ADN**

**UN/ID No** UN2811  
**Proper shipping name** Toxic solid, organic, n.o.s.  
**Hazard Class** 6.1  
**Packing Group** II  
**Classification code** T2  
**Special Provisions** 274, 614, 802  
**Description** UN2811, Toxic solid, organic, n.o.s., 6.1, II  
**Hazard label(s)** 6.1  
**Limited quantity (LQ)** 500 g  
**Equipment Requirements** PP, EP

## 15. Regulatory information

**International Inventories**

**TSCA** Not listed

**Note** \*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

**DSL/NDSL** Does not Comply  
**EINECS/ELINCS** Complies  
**ENCS** This product complies with ENCS:  
**IECSC** This product does not comply with china:  
**KECL** Does not Comply  
**PICCS** Does not Comply  
**AICS** All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**US Federal Regulations**

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**16. Other information****NFPA**

**Health hazards** 4

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -

**HMIS**

**Health hazards** 4

**Flammability** 0

**Physical hazards** 0

**Personal protection** X

**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

**Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
Organization for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

**Revision date** 16-February-2023  
**Revision Note** No information available.

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**

## Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
F1147	Fentanyl Citrate (CII), USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA:	2020632
Spectrum-New Brunswick, NJ:	2246824

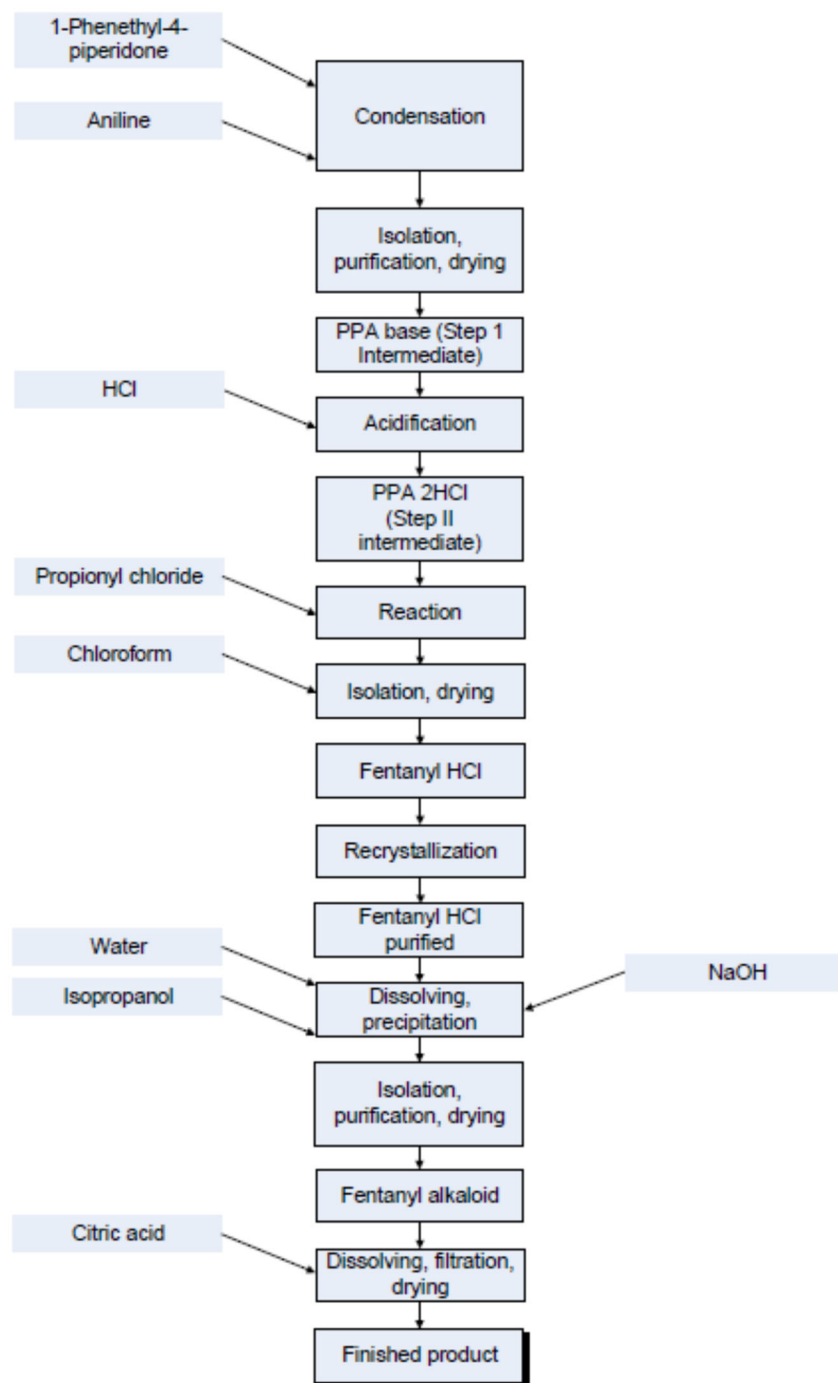
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,  
Quality Assurance  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.



## Manufacturing Process Flowchart - Fentanyl Citrate (CII), USP (Catalog No. F1147)



## F1147, Fentanyl Citrate (CII), USP

### Source Statement

The above-mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above-mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore BSE/TSE free.

### Allergen Statement

The above-mentioned catalog item does not contain any of the following:

- |             |                             |
|-------------|-----------------------------|
| ▪ Milk      | ▪ Cereals containing Gluten |
| ▪ Egg       | ▪ Celery                    |
| ▪ Fish      | ▪ Mustard                   |
| ▪ Shellfish | ▪ Sesame Seed               |
| ▪ Tree Nuts | ▪ Corn                      |
| ▪ Wheat     | ▪ Latex                     |
| ▪ Peanuts   | ▪ Sulfites > 10 ppm         |
| ▪ Soy       |                             |

### GMO Statement

The above-mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above-mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

### Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in the above-mentioned material.

### Animal Testing Statement

The above-mentioned catalog item has not been tested on animals by Spectrum Chemical Mfg. Corp.

### **Shelf Life Statement**

The above-mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

### **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above-mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Bisphenol A (BPA)
- Phthalates

## Elemental Impurities - Fentanyl Citrate (CII), USP (Catalog No. F1147)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cadmium	Cd	1	< 0.2 ppm
Lead	Pb	1	< 0.5 ppm
Arsenic	As	1	< 1.5 ppm
Selenium	Se	2B	< 8.0 ppm
Lithium	Li	3	< 25 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above-mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added, or known to be present in the above-mentioned material.

This information is subject to change and is intended for risk assessment only. It is the responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,  
Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

## Residual Solvents - Fentanyl Citrate (CII), USP (Catalog No. F1147)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above-mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,  
Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

## Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.

**Retest Date: 00-00-0000**



**DANGER**

- Fatal if swallowed, in contact with skin or if inhaled
- May cause drowsiness or dizziness • May cause an allergic skin reaction • May be habit forming.
- Do not eat, drink or smoke when using this product • Wear respiratory protection, protective gloves, protective clothing
- Do not get in eyes, on skin, or on clothing • Do not breathe dust • Use only outdoors or in a well-ventilated area. • Wash face, hands and any exposed skin thoroughly after handling
- Contaminated work clothing must not be allowed out of the workplace.

**FIRST AID:** Immediately call a POISON CENTER or physician. IF ON SKIN: Wash with plenty of water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

**KEEP FROM CHILDREN**

**WARNING:**  
Cancer and Reproductive Harm-  
[www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

**F1147**

**SIZ SY**

**Fentanyl Citrate**

USP

CAS 990-73-8

**CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only.  
**Read and understand the label and Safety Data Sheet (SDS) prior to use.**

DOT: UN2811, Toxic solid, organic, n.o.s.  
(fentanyl citrate), 6.1, PG II

**Chemical Emergency: (800)424-9300**

[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

$C_{22}H_{28}N_2O \cdot C_6H_8O_7$  F.W. 528.60

DEA Number Required.

Manufacturer/Supplier Code ..... ?  
Manufacturer Lot Number ..... ?

Assay (Dried Basis) ..... 98.0-102.0%

**MAXIMUM LIMITS**

Loss on Drying ..... 0.5%  
Residue on Ignition ..... 0.5%  
Elemental Impurities ..... As reported  
Organic Impurities:

Fentanyl N-oxide	0.15%
Fentanyl Related Compound G	0.15%
Fentanyl Pyruvyl Analog	0.15%
Fentanyl Related Compound E	0.15%
Fentanyl Butyryl Analog	0.15%
Any Unspecified Impurity	0.10%
Total Impurities	0.50%
Residual Solvents	To pass test

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

**Repackaged by Spectrum as:**  
Lot No. XQ####

B 8/K5GHS-A ?

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave.  
New Brunswick, NJ 08901  
732.214.1300

#### West Coast Facility:

14422 S. San Pedro St.  
Gardena, CA 90248  
310.516.8000