


## Section 1: Identification

<b>Common Name/Trade Name</b>	FENTANYL CITRATE USP	
<b>Supplier Information</b>	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	<b>IN CASE OF EMERGENCY:</b> Chemtrec 1 (800) 424-9300 (24 hours)
<b>Product Synonym(s)</b>	N-(1-phenethyl-4-piperidyl)propionanilide citrate (1:1) * N-Phenyl-N-[(1-(2-phenylethyl)-4-piperidinyl)propanamide, citrate salt * Fentanyl Citrate Analytical Research Standard (FOR R&D USE ONLY)	
<b>Relevant Use(s) of Product</b>	Manufacture or Compounding of Substances	

## Section 2: Hazards Identification

<b>Classification of Substance or Mixture</b>	Acute toxicity, oral Category 2, Acute toxicity, dermal Category 2, Acute toxicity, inhalation Category 2, Specific target organ toxicity, single exposure Category 3 narcotic effects	
<b>Signal Word</b>	Danger	
<b>Hazard Statement(s)</b>	H300 Fatal if swallowed H310 Fatal in contact with skin H330 Fatal if inhaled H336 May cause drowsiness or dizziness	
<b>Pictogram(s)</b>		
<b>Precautionary Statement(s)</b>	P260 Do not breathe dust/fume/gas/mist/vapours/spray. P262 Do not get in eyes, on skin, or on clothing. P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves/protective clothing/eye protection/face protection. P285 In case of inadequate ventilation wear respiratory protection. P301+P310 IF SWALLOWED Immediately call a POISON CENTER or doctor/physician. P302+P352 IF ON SKIN Wash with soap and water. P304+P340 IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing. P310 Immediately call a POISON CENTER or doctor/physician. P310 Immediately call a POISON CENTER or doctor/physician. P312 Call a POISON CENTER or doctor/physician if you feel unwell. P330 Rinse mouth. P361 Remove/Take off immediately all contaminated clothing. P363 Wash contaminated clothing before reuse. P403+P233 Store in a well ventilated place. Keep container tightly closed. P405 Store locked up. P501 Dispose of contents/container to an approved waste disposal plant.	
<b>Hazards Not Otherwise Classified</b>	None known.	
<b>Ingredient(s) with Unknown Toxicity</b>	No data available	

## Section 3: Composition/Information on Ingredients

<b>Chemical Name</b>	FENTANYL CITRATE
<b>Common Name</b>	N-(1-phenethyl-4-piperidyl)propionanilide citrate (1:1) N-Phenyl-N-[(1-(2-phenylethyl)-4-piperidinyl) propanamide, citrate salt Fentanyl Citrate Analytical Research Standard (FOR R&D USE ONLY)
<b>CAS Number</b>	990-73-8
<b>Impurities and/or Stabilizing Additives</b>	No data available

## Section 4: First Aid Measures

<b>General Advice</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Take off all contaminated clothing immediately. In case of shortness of breath, give oxygen. Keep victim warm. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.
<b>If Inhaled</b>	If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim 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. Call a physician or poison control center immediately
<b>In Case of Skin Contact</b>	Rinse skin with water/shower. Remove and isolate contaminated clothing and shoes. Call a physician or poison control center immediately. Wash clothing separately before reuse
<b>In Case of Eye Contact</b>	Immediately flush eyes with plenty of water for at least 15 minutes. If a contact lens is present, DO NOT delay irrigation or attempt to remove the lens. Continue rinsing. Call a physician or poison control center immediately.
<b>If Swallowed</b>	If swallowed: Immediately call a poison center/doctor. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting without advice from poison control center. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
<b>Most Important Symptoms and Effects</b>	Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Indication of immediate medical attention and special treatment needed The principle sign of serious overdose to fentanyl include stupor and respiratory depression. Treatment for these effects due to fentanyl is the same as for overdose by other opioids: airway maintenance, ventilation support, and administration of a narcotic antagonist such as naloxone (Narcan <sup>®</sup> ) beginning with 0.4 to 2 mg intravenously and repeating every three minutes as clinically indicated. Intramuscular or subcutaneous administration may be necessary if the intravenous route is not available.

## Section 5: Fire Fighting Measures

<b>Suitable Extinguishing Media</b>	Flammable properties Not flammable by OSHA criteria. Dust may form explosive mixture with air. Suitable extinguishing media Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ). Unsuitable extinguishing media: None known.
<b>Special Hazards Arising From the Substance/Mixture</b>	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed such as: Carbon oxides. Nitrogen Oxides (NO <sub>x</sub> ).
<b>Special PPE and/or Precautions for Firefighters</b>	Wear full protective clothing, including helmet, self-contained positive pressure or pressure demand breathing apparatus, protective clothing and face mask. Fire-fighting equipment/instructions In case of fire and/or explosion do not breathe fumes. In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk. As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear. Specific methods Cool containers exposed to flames with water until well after the fire is out. General fire hazards No unusual fire or explosion hazards noted.

## Section 6: Accidental Release Measures

<b>Personal Precautions, Protective Equipment and Emergency Procedures</b>	Immediately evacuate personnel to safe areas. Ensure adequate ventilation. Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate protective equipment and clothing during clean-up. Avoid contact with spilled material. Avoid inhalation of dust from the spilled material. Ventilate closed spaces before entering them.
<b>Methods and Materials Used for Containment</b>	Stop the flow of material, if this is without risk. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Prevent entry into waterways, sewer, basements or confined areas. Do not flush to sewer. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Collect dust using a vacuum cleaner equipped with HEPA filter. Use only non-sparking tools. Clean surface thoroughly to remove residual contamination. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.
<b>Cleanup Procedures</b>	Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Prevent entry into waterways, sewer, basements or confined areas. Do not flush to sewer. Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation. Collect dust using a vacuum cleaner equipped with HEPA filter. Use only non-sparking tools. Clean surface thoroughly to remove residual contamination. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented.

## Section 7: Handling and Storage

<b>Precautions for Safe Handling</b>	Do not use in areas without adequate ventilation. DO NOT handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Minimize dust generation and accumulation. Keep formation of airborne dusts to a minimum. Dust may form explosive mixture with air. Provide appropriate exhaust ventilation at places where dust is formed. Use personal protective equipment as required. Do not breathe dust. Do not ingest. Do not get this material in contact with eyes. Do not get this material in contact with skin. Do not get this material on clothing. Wash thoroughly after handling. Take precautionary measures against static discharges. Static electricity and formation of sparks must be prevented. All equipment used when handling the product must be grounded. Ground and bond containers when transferring material. Use non-sparking tools and explosion-proof equipment. Avoid release to the environment. Handle and open container with care.
<b>Conditions for Safe Storage</b>	For storage condition, see finished product label. Store locked up. Keep container tightly closed. Store in a well-ventilated place. Guard against dust accumulation of this material. Keep away from heat and sources of ignition. This material can accumulate static charge which may cause spark and become an ignition source. Prevent electrostatic charge build-up by using common bonding and grounding techniques. Use care in handling/storage. Store in accordance with local/regional/national/international regulation. CONTROLLED SUBSTANCE: Location of storage area must comply with all Drug Enforcement Administration or competent authority regulations.

## Section 8: Exposure Controls/Personal Protection

<b>Components with Workplace Control Parameters</b>	FENTANYL CITRATE (CAS OEB 3 OEB 990-73-8) OEG 0.7 $\mu\text{g}/\text{m}^3$ 8-hour time-weighted average STEG 2 $\mu\text{g}/\text{m}^3$ 15-minute average; skin notation. Biological limit values No biological exposure limits noted for the ingredient(s). Exposure guidelines No exposure standards allocated.
<b>Appropriate Engineering Controls</b>	Explosion-proof general and local exhaust ventilation. To prevent contamination and overexposure, no open handling of powder should be allowed. Powder handling operations are to be done in a powder weighing hood, a glove box, or other equivalent ventilated containment system. In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used. Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs. Wash hands after handling and before eating. When using, do not eat, drink or smoke. Do not breathe dust. Do not get in eyes. Do not get this material in contact with skin. Do not get this material on clothing. Wash hands before breaks and immediately after handling the product. Handle in accordance with good industrial hygiene and safety practice.
<b>PPE - Eye/Face Protection</b>	Chemical goggles are recommended. Provide eyewash station and safety shower.
<b>PPE - Skin Protection</b>	Wear protective gloves.
<b>PPE - Body Protection</b>	Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Thermal hazards Wear appropriate thermal protective clothing, when necessary.
<b>PPE - Respiratory Protection</b>	An air-purifying respirator (P95 or other type providing a higher level of protection) should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.). If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.

## Section 9: Physical and Chemical Properties

<b>Appearance</b>	Appearance: Granular. Powder. Physical state: Solid. Form: Powder. Color: White.
<b>Upper/Lower Flammability or Explosive Limits</b>	Not available
<b>Odor</b>	Odorless
<b>Vapor Pressure</b>	Not available
<b>Odor Threshold</b>	Not available
<b>Vapor Density</b>	Not available
<b>pH</b>	Not available
<b>Relative Density</b>	Not available
<b>Melting Point/Freezing Point</b>	296.6 - 305.6 °F (147 - 152 °C)
<b>Solubility</b>	Not available
<b>Initial Boiling Point and Boiling Range</b>	Not available
<b>Flash Point</b>	Not available
<b>Evaporation Rate</b>	Not available
<b>Flammability (Solid, Gas)</b>	Not available
<b>Partition Coefficient</b>	Not available
<b>Auto-Ignition Temperature</b>	Not available
<b>Decomposition Temperature</b>	Not available
<b>Viscosity</b>	Not available

## Section 10: Stability and Reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability</b>	Discoloration upon exposure to light.
<b>Possibility of Hazardous Reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to Avoid</b>	Avoid spread of dust. Heat, flames and sparks. Light.
<b>Incompatible Materials</b>	Oxidizing agents. Strong acids.
<b>Hazardous Decomposition Products</b>	No hazardous decomposition products are known.

## Section 11: Toxicological Information

<b>Acute Toxicity - LD50 Oral</b>	LD50 Rat Oral Acute 18 mg/kg (for Fentanyl). Very toxic if swallowed. Fatal if swallowed. Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal. Dizziness. May cause central nervous system depression. Large doses can lead to respiratory or cardiac arrest and death.
<b>Acute Toxicity - Inhalation</b>	No data available. Fatal if inhaled. Narcotic effect. May cause typical symptoms of narcosis (see Ingestion.) Dust irritates the respiratory system, and may cause coughing and difficulties in breathing. Inhalation of powder/dust may cause lung edema.
<b>Acute Toxicity - Dermal</b>	No data available. Fatal in contact with skin. May produce narcotic effects if absorbed through skin. Symptoms may parallel ingestion.
<b>Acute Toxicity - Eye</b>	No data available. Dust or powder may irritate eye tissue. May have a strong narcotic effect (pupil constriction) and the eye may serve as an absorption route into the body.
<b>Skin Corrosion/Irritation</b>	Due to lack of data the classification is not possible.
<b>Serious Eye Damage/Irritation</b>	Due to lack of data the classification is not possible.
<b>Respiratory or Skin Sensitization</b>	Due to lack of data the classification is not possible.
<b>Germ Cell Mutagenicity</b>	Due to lack of data the classification is not possible.
<b>Carcinogenicity IARC</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Not listed.
<b>Carcinogenicity ACGIH</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA..
<b>Carcinogenicity NTP</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
<b>Carcinogenicity OSHA</b>	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Not regulated. Not available.
<b>Reproductive Toxicity</b>	Due to lack of data the classification is not possible.
<b>Specific Target Organ Toxicity - Single Exposure</b>	Narcotic effects.
<b>Specific Target Organ Toxicity - Repeated Exposure</b>	Due to lack of data the classification is not possible.
<b>Aspiration Hazard</b>	Due to lack of data the classification is not possible.

## Section 12: Ecological Information

<b>Toxicity</b>	This product has no known eco-toxicological effects.
<b>Persistence and Degradability</b>	No data is available on the degradability of this product.
<b>Bio-accumulative Potential</b>	Not established.
<b>Mobility in Soil</b>	Not available.
<b>Other Adverse Effects</b>	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

## Section 13: Disposal Considerations

<b>Waste Treatment Methods Product</b>	Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of contents/container (in accordance with related regulations).
<b>Waste Treatment Methods Packaging</b>	Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of contents/container (in accordance with related regulations). Hazardous waste code Not regulated. Waste from residues / unused products Not available. Contaminated packaging Not available
<b>Special Precautions Landfill or Incinerations</b>	No data available
<b>Other Information</b>	No data available

## Section 14: Transport Information

<b>UN Number</b>	UN2811
<b>UN Proper Shipping Name</b>	Toxic solids, organic, n.o.s. (N-(1-Phenethyl-4-piperidyl)propionanilide citrate)
<b>Transport Hazard Class(es)</b>	6.1
<b>Packaging Group</b>	II
<b>Environmental Hazards</b>	No

## Section 15: Regulatory Information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. TSCA exempt status. TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050) Not listed. CERCLA (Superfund) reportable quantity None Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - Yes Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazardous substance Not listed. SARA 311/312 Hazardous chemical Yes Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Safe Drinking Water Act (SDWA) Not regulated. Drug Enforcement Administration (DEA) (21 CFR 1308.11-15) Schedule II - 9801 US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. US. Massachusetts RTK - Substance List Not regulated. US. New Jersey Worker and Community Right-to-Know Act Not listed. US. Pennsylvania Worker and Community Right-to-Know Law Not listed. US. Rhode Island RTK Not regulated. US. California Proposition 65 Not Listed. International Inventories Country(s) or region Inventory name On inventory (yes/no)\* Australia Australian Inventory of Chemical Substances (AICS) Yes Canada Domestic Substances List (DSL) No Canada Non-Domestic Substances List (NDSL) No China Inventory of Existing Chemical Substances in China (IECSC) No Europe European Inventory of Existing Commercial Chemical Substances (EINECS) Europe European List of Notified Chemical Substances (ELINCS) No Japan Inventory of Existing and New Chemical Substances (ENCS) No Korea Existing Chemicals List (ECL) No New Zealand New Zealand Inventory Yes Country(s) or region Inventory name On inventory (yes/no)\* Philippines Philippine Inventory of Chemicals and Chemical Substances No (PICCS) United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No \*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## Section 16: Other Information

<b>Additional Information</b>	N/A
<b>Prepared By</b>	Lisa Russell
<b>Revision Date</b>	01/11/2019 16:32

### Disclaimer

Letco Medical, LLC believes that the above information is correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. If the product is used as a component in another product, this information may not be applicable. NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE INFORMATION PROVIDED ABOVE. Letco Medical shall not be held liable for any loss or damage resulting from handling, storage, use or from contact with the above product.