

1. Product and Company Identification

Material name	FENTANYL CITRATE
Version #	03
Revision date	04-11-2012
CAS #	990-73-8
Synonym(s)	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)
Manufacturer information	Mallinckrodt 675 McDonnell Blvd. Hazelwood, MO 63042 24 Hour Emergency 314-654-1600 Chemtrec 800-424-9300 Customer Service 888-744-1414
Item code	0662, 0666, 1130, 1205, 1333, 1344, 9011, 9133

2. Hazards Identification

Emergency overview	DANGER Potent Narcotic. May be fatal if swallowed. May be fatal if inhaled. May be fatal if absorbed through skin. Causes central nervous system effects. Dust may form explosive mixture with air.
OSHA regulatory status	This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication).
Potential health effects	
Routes of exposure	Inhalation. Ingestion. Skin contact. Eye contact.
Eyes	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. Do not get this material in contact with eyes.
Skin	This product may be fatal if it is absorbed through the skin. May produce narcotic effects if absorbed through skin. Symptoms may parallel ingestion.
Inhalation	May be 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.
Ingestion	Highly toxic. May be 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. Do not ingest.
Target organs	Central nervous system. Heart.
Chronic effects	Causes central nervous system effects. May lead to habituation or addiction.
Signs and symptoms	Narcosis. Decrease in motor functions. Respiratory disorder.

3. Composition / Information on Ingredients

Components	CAS #	Percent
FENTANYL CITRATE	990-73-8	100

4. First Aid Measures

First aid procedures	
Eye contact	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. Get medical attention immediately.

Skin contact	Immediately flush skin with plenty of water. Remove and isolate contaminated clothing and shoes. Get medical attention immediately. Wash clothing separately before reuse.
Inhalation	If gas/fume/vapor/dust/mist 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. Get medical attention immediately.
Ingestion	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. 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.
Notes to physician	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®) 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.
General advice	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.

5. Fire Fighting Measures

Flammable properties	As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source. Dust may form explosive mixture with air.
Extinguishing media	
Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Fire fighting equipment/instructions	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. Follow handling guidance appropriate for OEB-3 potent compounds, (see section 7).

6. Accidental Release Measures

Personal precautions	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. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7).
Environmental precautions	Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.
Methods for containment	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.
Methods for cleaning up	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. For waste disposal, see section 13 of the MSDS.

7. Handling and Storage

Handling

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. Do not breathe dust. Keep formation of airborne dusts to a minimum. Provide appropriate exhaust ventilation at places where dust is formed. Use personal protective equipment as required. 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. All equipment used when handling the product must be grounded. Ground and bond containers when transferring material. When using, do not eat, drink or smoke. Avoid release to the environment. Handle and open container with care.

Storage

Store locked up. Storage temperature: between 20°C and 25°C (68-77°F). 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.

Further information

CONTROLLED SUBSTANCE: Location of storage area must comply with all Drug Enforcement Agency regulations.

Fentanyl Citrate has potent pharmacological activity and is classified as an OEB-3* material. Handling practices for OEB-3 substances are described below.

LABORATORY: *Wear appropriate gloves, lab coat, and safety glasses. Use good lab practices. *A designated area is required for handling compounds.

*Work surfaces are to be cleaned daily. If lab bench absorbent paper is used, it is to be changed at least daily.

*High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.

*Develop cleaning procedures and techniques that limit potential exposure.

*POWDERS HANDLING: To prevent contamination and overexposure, no open handling of powder should be allowed. Powder handling operations are to be done in a powders 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. 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.). Powder should be put into solution or a closed or covered container after handling. 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.

*SOLUTIONS HANDLING: *Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolization. If the procedures have a potential for aerosolization, and air-purifying respirator (P95 or other type providing a higher level of protection) is to be worn by all personnel in the immediate area.

*Solutions used for procedures where aerosolization may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation. In situations where this is not feasible (may include animal dosing), an air-purifying respirator (P95 or other type providing a higher level of protection) is to be worn by all personnel in the immediate area.

*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.

*Ensure gloves are protective against solvents in use.

- *PILOT PLANT and PRODUCTION: *Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties. Use good manufacturing practices (i.e., cGMPs).
- *Protective garment (coveralls, Tyvek, lab coat) is not to be worn outside the work area.
- *Clean/dirty/decontamination areas are to be established.
- *Negative/positive air pressure relationships and buffer zones required (i.e., ante-room/degowning room/airlock).
- *Area access is to be restricted.
- *High-energy operations such as milling, particle sizing, spraying or fluidizing should be done within an approved emission control or containment system.
- *Develop cleaning procedures and techniques that limit potential exposure.

- *POWDERS HANDLING: *Emphasis is to be placed on closed material transfer systems and process containment, with no open handling of powders. Use enclosures and containment measures to reduce potential exposures.
- *Use a powered, air-purifying respirator (PAPR) with HEPA cartridges or a supplied-air respirator (SAR) until processes have been monitored to show that respiratory protection is not required.

- *SOLUTIONS HANDLING: *Enclose systems where possible. Processing tanks are to be kept covered. Process samples should be taken from sample ports if feasible.
- *Wear a P95 Dust/Mist respirator or a respirator supplying a higher level of protection until processes have been monitored to show that respiratory protection is not required.
- *Ensure gloves are protective against solvents in use.

- *OEB - Mallinckrodt's Occupational Exposure Band: The classification of a compound or pharmaceutical ingredient into one of four ordinal categories of increasing potency and toxicity. This rating assigns a set of pre-determined handling and containment practices to a compound until a quantitative OEL is established.

8. Exposure Controls / Personal Protection

Occupational exposure limits

Mallinckrodt

Material	Type	Value	Form
FENTANYL CITRATE (990-73-8)	OEB	3.0000	
	OEG	0.7000 µg/m3	8-hour time-weighted average
	STEG	2.0000 µg/m3	15-minute average; skin notation

Engineering controls

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. See Section 7 for additional information on proper handling and venting requirements for potent compounds.

Personal protective equipment

Eye / face protection

Chemical goggles are recommended. Provide eyewash station and safety shower.

Skin protection

Wear appropriate gloves; lab coat, nylon coveralls or disposable Tyvek suit; safety glasses, safety shoes, and disposable booties.

Respiratory protection

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. See Section 7 for additional information on proper handling and respirator recommendations for potent compounds.

General hygiene considerations

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 after handling and before eating. Handle in accordance with good industrial hygiene and safety practice. See Section 7 for additional information on occupational control measures appropriate for OEB-3 potent compounds.

9. Physical & Chemical Properties

Appearance	Granular. Powder.
Physical state	Solid.
Form	Powder.
Color	White.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Boiling point	Not available.
Melting point/Freezing point	296.6 - 305.6 °F (147 - 152 °C)
Solubility (water)	Not available.
Specific gravity	Not available.
Relative density	Not available.
Flash point	Not available.
Flammability limits in air, upper, % by volume	Not available.
Flammability limits in air, lower, % by volume	Not available.
Auto-ignition temperature	Not available.
Molecular weight	528.61
Molecular formula	C ₂₂ H ₂₈ N ₂ O.C ₆ H ₈ O ₇
Dust Electrostatic Properties	
Minimum Ignition Energy (Cloud)	10 - 25 mJ
Dust Explosion Properties	
dP/dT	812 bar/s
Kst	220 bar.m/s
Minimum Explosible Concentration	30 - 40 g/m ³
Minimum Ignition Temperature-Cloud	752 - 788 °F (400 - 420 °C)
Minimum Ignition Temperature-Layer	> 752 °F (> 400 °C)
Pmax	8.3 bar

10. Chemical Stability & Reactivity Information

Chemical stability	Discoloration upon exposure to light.
Conditions to avoid	None under normal conditions.
Incompatible materials	Not available.
Hazardous decomposition products	Carbon oxides. Nitrogen oxides (NO _x).

Possibility of hazardous reactions

Hazardous polymerization does not occur.

11. Toxicological Information

Toxicological data

Product

Test Results

FENTANYL CITRATE (990-73-8)

Acute Oral LD50 Rat: 18 mg/kg (for Fentanyl)

Acute effects

May be fatal if inhaled, absorbed through skin, or swallowed.

Local effects

Narcotic effect. Exposure may cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, constipation, respiratory depression; also tolerance, dependence and withdrawal.

Chronic effects

May cause central nervous system disorder (e.g., narcosis involving a loss of coordination, weakness, fatigue, mental confusion and blurred vision) and/or damage. Chronic exposure may lead to tolerance, dependence, and unpleasant withdrawal symptoms upon abrupt discontinuation of use (e.g., sweating, restlessness, irritability, hallucinations).

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Further information

Fentanyl readily passes across the placenta to the fetus.

12. Ecological Information

Ecotoxicity

This product has no known eco-toxicological effects.

Environmental effects

Not classified as an environmental hazard. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Persistence and degradability

No data is available on the degradability of this product.

13. Disposal Considerations

Disposal instructions

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. Follow handling guidance appropriate for OEB-3 potent compounds, (see Section 7). Dispose of contents/container (in accordance with related regulations).

14. Transport Information

DOT

Basic shipping requirements:

UN number UN2811
Proper shipping name Toxic solids, organic, n.o.s. (N-(1-Phenethyl-4-piperidyl)propionanilide citrate)
Hazard class 6.1
Packing group II

Additional information:

Special provisions IB8, IP2, IP4, T3, TP33

Basic shipping requirements:

Labels required 6.1

Additional information:

Packaging exceptions 153
Packaging non bulk 212
Packaging bulk 242
ERG number 154

IATA

Basic shipping requirements:

UN number 2811
Proper shipping name Toxic solid, organic, n.o.s. (N-(1-Phenethyl-4-piperidyl)propionanilide citrate)
Hazard class 6.1
Packing group II

Additional information:

ERG code 6L

IMDG

Basic shipping requirements:

UN number 2811
Proper shipping name TOXIC SOLID, ORGANIC, N.O.S. (N-(1-PHENETHYL-4-PIPERIDYL)PROPIONANILIDE CITRATE)
Hazard class 6.1
Packing group II



DOT



IATA



IMDG

15. Regulatory Information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
CERCLA/SARA Hazardous Substances - Not applicable.
TSCA exempt status.

Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2))

Not regulated

DEA Essential Chemical Code Number

Not regulated

Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Not regulated

DEA Exempt Chemical Mixtures Code Number

Not regulated

CERCLA (Superfund) reportable quantity

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance No

Section 311 hazardous chemical No

Drug Enforcement Administration (DEA) (21 CFR 1308.11-15) Schedule II - 9801

Inventory status

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

Country(s) or region	Inventory name	On inventory (yes/no)*
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
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
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
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)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

16. Labeling Info

Label Hazard Warning	DANGER! Potent Narcotic. May be fatal if inhaled, absorbed through skin, or swallowed. Causes central nervous system effects.
Label Precautions	Do not breathe dust. Do not get in eyes, on skin, or on clothing. Keep container closed. Use only with adequate ventilation. Wash thoroughly after handling. Wear suitable protective clothing and gloves.
Label First Aid	Immediately flush eyes with plenty of water for at least 15 minutes. Immediately flush skin with plenty of water. If gas/fume/vapor/dust/mist from the material is inhaled, remove the affected person immediately to fresh air. Get medical attention immediately. Do not use mouth-to-mouth method if victim inhaled the substance. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. 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 thoroughly. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

17. Other Information

NFPA ratings	Health: 4 Flammability: 0 Instability: 0
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