SAFETY DATA SHEETS

This SDS packet was issued with item:

078905657

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078671584



Material Safety Data Sheet

 Revision date:
 1/19/2012

 Print date:
 1/19/2012

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: Fentanyl Citrate Injection, USP

Product Codes: NDC 0641-6024-01 NDC 0641-6024-10 NDC 0641-6025-01

NDC 0641-6025-10 NDC 0641-6026-01 NDC 0641-6026-05 NDC 0641-6027-01 NDC 0641-6027-25 NDC 0641-6028-01 NDC 0641-6028-25 NDC 0641-6029-01 NDC 0641-6029-25

NDC 0641-6030-01

Synonyms: None Chemical Family: Analgesic

Product Type: Regulated Prescription Drug

Container Information: 2, 5, and 20 ml ampuls and 2, 5, 20, and 50 ml vials

Product Use: Pharmaceutical.

Supplier:

WEST-WARD PHARMACEUTICALS

EATONTOWN, NJ 07724

Emergency telephone number: CHEMTREC: USA & Canada (800) 424-9300 OUTSIDE USA +1 703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Fentanyl Citrate 990-73-8	0.005	None	None
Water 7732-18-5	>99	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: HARMFUL IF SWALLOWED. Central Nervous System depression.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions.

Ingestion: Harmful if swallowed.

Skin contact: No known effect according to our database.

Eye contact: No known effect according to our database.

4. FIRST AID MEASURES

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration, If breathing

is difficult, give oxygen. Get medical attention if symptoms appear.

Skin contact: In case of contact, immediately flush skin with plenty of water. Remove

contaminated clothing and shoes. Wash clothing before reuse. Get medical

attention if irritation develops.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give

anything by mouth to an unconscious person. If large quantities of this material are

swallowed, call a physician immediately.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Get medical attention if irritation develops.

Notes to physician: See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media: Use foam or all purpose dry chemicals to extinguish.

Special protective equipment for firefighters: Fire fighters should wear positive pressure self-contained

breathing apparatus (SCBA) and full turnout gear.

Specific methods: No information available.

Flash point:

Autoignition temperature:

Flammable limits in air-lower (%):

Flammable limits in air-upper (%):

Not determined
Not available
Not available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Use suitable protective equipment (Section 8). Follow all fire fighting procedures

(Section 5).

Environmental precautions: No information available.

Methods for cleaning up: For small spills add absorbent (soil may be used in the absence of other suitable

materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure

runoff does not reach a waterway. Place spilled material in an appropriate container

for disposal.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Wash thoroughly after handling.

Storage:

Technical Keep containers tightly closed in a dry, cool and well-ventilated place. Store at room

measures/Storage conditions: temperature between 20°C and 25°C (68°F and 77°F). Protect from light. Follow

Schedule II controlled substance requirements.

Incompatible products: No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Fentanyl Citrate 990-73-8	None	None	None	None	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:

Respiratory protection: No personal respiratory protective equipment normally required.

Use chemical resistant, impervious gloves. Hand protection:

Work uniform or laboratory coat. Additional body garments should be used based Skin and body protection:

upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to

avoid exposed skin surfaces.

Eye protection: Eye protection not required for normal final product use. Safety glasses with side-

shields are recommended for laboratory and manufacturing use.

PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid

Aqueous solution Appearance:

Color: Colorless Odor: Not available. 4.0 - 7.5pH: Molecular weight: Not applicable Boiling point/range: Not available. Melting point/range: Not available. Density: Not available. Vapor pressure: Not available. Evaporation rate: Not available. Soluble in water. Solubility: Not available.

Partition coefficient (n-

octanol/water):

Not available. Viscosity:

% Volatile by Volume: Not available.

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Polymerization: Not applicable Not available. Hazardous decomposition

products:

Materials to avoid: Not available.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Fentanyl Citrate	Oral LD50 Rat: 18 mg/kg; Oral LD50 Mouse: 368 mg/kg; Intravenous LD50 Rat: 0.99 mg/kg;
990-73-8	Intravenous LD50 Mouse: 10.1 mg/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

Acute toxicity: Signs and symptoms of overexposure to narcotic analgesics may include respiratory

depression, drowsiness progressing to stupor or coma, rash, itching, headache, nausea, vomiting, muscle relaxation, cold and clammy skin, slow heart rate, low blood pressure, apnea, circulatory collapse, cardiac arrest, and possibly death.

Chronic toxicity: Target Organs: Nervous system.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on

the product itself.

Mutagenic effects: No data is available on the product itself.

Reproductive toxicity: May impair fertility based on animal data. Considered fetotoxic. See patient package

insert for additional information.

FDA Pregnancy Category C

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Fentanyl Citrate 990-73-8	None.	None.	None.	None.
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Follow schedule II controlled substance requirements.

Waste from residues/

unused products Waste disposal must be in accordance with appropriate Federal, State, and

local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name: None **UN Number:** None DOT Packing Group: None **DOT Hazard class:** None

TDG (Canada):

TDG Proper shipping name: None TDG UN/NA Number: None TDG Packing Group: None TDG Hazard class: None

ADR/RID:

ADR Official Transport Name: None ADR Proper shipping name: None ADR UN/NA number: None ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None IATA UN NUMBER None IATA Primary Hazard None IATA Packing group: None ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None IMDG Hazard Class and Division: None IMDG Packing Group: None IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

The product is exempt from TSCA, it is FDA Regulated TSCA Inventory List -

OTHER REGULATIONS:

Japanese Inventory (ENCS) This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Fentanyl Citrate	0.005	Not Listed	Not Listed	Not Listed	Not Listed
Water	>99	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop 65:	Minnesota Right-To - Know:	Florida Right- to-Know Reporting List:	Right-to-Know		Pennsylvania Right-to-Know:	New Jersey Right-to- Know:
Fentanyl Citrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List -This product does not comply with DSL

Risk Phrases:

EU EINECS List -This product complies with EINECS

Not determined Safety Phrases: Not Determined

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

Updated company name from Baxter to West-Ward. Updated NDC codes

Additional information:

Not Available.

Prepared by: West-Ward Pharmaceuticals

To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

End of safety data sheet

SAFETY DATA SHEET

Fentanyl Citrate Injection, USP



Section 1. Identification

GHS product identifier

: Fentanyl Citrate Injection, USP

Synonyms

: Not available.

Product code

: NDC 0641-6024-01 NDC 0641-6024-10 NDC 0641-6025-01 NDC 0641-6025-10 NDC 0641-6026-01 NDC 0641-6026-05 NDC 0641-6027-01 NDC 0641-6027-25 NDC 0641-6028-01 NDC 0641-6028-25 NDC 0641-6029-01 NDC 0641-6029-25

NDC 0641-6030-01

Chemical family

: Analgesic.

Product type

: Regulated prescription drug.

Container information

: 2, 5, and 20 ml ampuls and 2, 5, 20, and 50 ml vials.

Relevant identified uses of the substance or mixture and uses advised against

Pharmaceuticals.

Supplier's details

: WEST-WARD PHARMACEUTICALS

EATONTOWN, NJ 07724

Emergency telephone number (with hours of

operation)

: CHEMTREC, U.S.: 1-800-424-9300 International: +1-703-527-3877

Section 2. Hazards identification

OSHA/HCS status

: While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture

: Not classified.

GHS label elements

Signal word

: No signal word.

Hazard statements

: No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.
Response : Not applicable.
Storage : Not applicable.
Disposal : Not applicable.
Hazards not otherwise : None known.

classified



Section 3. Composition/information on ingredients

Substance/mixture
Other means of identification

: Not available.

CAS number/other identifiers

Ingredient name	%	CAS number
Water	60 - 100	7732-18-5
Fentanyl dihydrogen citrate	0 - 0.1	990-73-8

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately

: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation

occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get

medical attention if symptoms occur.

Skin contact : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur.

Ingestion: Wash out mouth with water. Remove victim to fresh air and keep at rest in a position

comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 Ingestion
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large

quantities have been ingested or inhaled.

Specific treatments: No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)





Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing

media

Unsuitable extinguishing

media

: Use an extinguishing agent suitable for the surrounding fire.

: None known.

Specific hazards arising from the chemical

Hazardous thermal decomposition products

: No specific fire or explosion hazard.

: No specific data.

Special protective actions for fire-fighters

Special protective equipment for fire-fighters

: No special protection is required.

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders:

: If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Spill

: Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures
Advice on general
occupational hygiene

- : Put on appropriate personal protective equipment (see Section 8).
- : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.





Section 7. Handling and storage

Conditions for safe storage, including any incompatibilities

: Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

Appropriate engineering controls

: No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Environmental exposure controls

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with sideshields.

Skin protection

Hand protection

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

: Use a properly fitted, air-purifying or supplied air respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.



Section 9. Physical and chemical properties

Appearance

Physical state : Liquid. [Aqueous solution.]

Color : Colorless.

Odor : Not available.

Odor threshold : Not available.

pH : 4.5 to 7.5

Melting point : Not available.

Boiling point : Not available.

Flash point : Not applicable.

Burning time : Not applicable.

Burning rate : Not applicable.

Evaporation rate : Not available.

Flammability (solid, gas)
Lower and upper explosive

(flammable) limits

Not available.Not available.

Vapor pressure : Not available.
Vapor density : Not available.
Relative density : Not available.

Solubility : Easily soluble in the following materials: cold water and hot water.

Solubility in water : Not available.

Partition coefficient: n- : Not available.

octanol/water

Auto-ignition temperature: Not available.Decomposition temperature: Not available.SADT: Not available.Viscosity: Not available.

Section 10. Stability and reactivity

Reactivity: No specific test data related to reactivity available for this product or its ingredients.

Chemical stability: The product is stable.

Possibility of hazardous reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials.

Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should

not be produced.



Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

There is no data available.

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely

routes of exposure

: Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate

: No known significant effects or critical hazards.

effects

Potential delayed effects

: No known significant effects or critical hazards.

Long term exposure

Potential immediate

: No known significant effects or critical hazards.

effects





Section 11. Toxicological information

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.
 Carcinogenicity : No known significant effects or critical hazards.
 Mutagenicity : No known significant effects or critical hazards.
 Teratogenicity : No known significant effects or critical hazards.
 Developmental effects : No known significant effects or critical hazards.
 Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

There is no data available.

Other information : FDA Class C

Section 12. Ecological information

Toxicity

There is no data available.

Persistence and degradability

There is no data available.

Bioaccumulative potential

There is no data available.

Mobility in soil

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.





Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG: Not applicable.

Special precautions for user : Transport within user's premises: always transport in closed containers that are

upright and secure. Ensure that persons transporting the product know what to do in the

event of an accident or spillage.

Transport in bulk according : Not available.

to Annex II of MARPOL 73/78 and the IBC Code

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112

(b) Hazardous Air **Pollutants (HAPs)** : Not listed

Clean Air Act Section 602

Class I Substances

: Not listed

Clean Air Act Section 602

: Not listed

Class II Substances

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312





Section 15. Regulatory information

Classification : Not applicable.

Composition/information on ingredients

No products were found.

State regulations

Massachusetts: None of the components are listed.New York: None of the components are listed.New Jersey: None of the components are listed.Pennsylvania: None of the components are listed.

California Prop. 65

No products were found.

International regulations

International lists : Australia inventory (AICS): All components are listed or exempted.

China inventory (IECSC): Not determined.

Japan inventory: Not determined. **Korea inventory**: Not determined.

Malaysia Inventory (EHS Register): Not determined.

New Zealand Inventory of Chemicals (NZIoC): All components are listed or exempted.

Philippines inventory (PICCS): Not determined. Taiwan inventory (CSNN): Not determined.

Chemical Weapons

Convention List Schedule

I Chemicals

Chemical Weapons : Not listed

Convention List Schedule

II Chemicals

Chemical Weapons

Convention List Schedule

III Chemicals

: Not listed

: Not listed

Section 16. Other information

History

Date of issue mm/dd/yyyy : 09/15/2013

Version : 1

Revised Section(s) : Not applicable.

Prepared by : KMK Regulatory Services Inc.

Key to abbreviations : ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships,

1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)

UN = United Nations





Section 16. Other information

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

