

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Fentanyl Citrate Injection, 50 mcg per mL**
Manufacturer Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: September 08, 2016
SDS Revision Date: May 16, 2019

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word:

DANGER.

GHS Class:

Acute Oral Toxicity. Category 2.
 Specific Target Organ Toxicity - STOT, Single Exposure SE. category 1 (Oral, Respiratory system).
 Eye Irritation. Category 2.
 Skin Sensitization. category 1.
 Specific Target Organ Toxicity - STOT, Single Exposure SE. Category 3.
 Reproductive toxicity. Effects on or via lactation.

Hazard Statements:

Fatal if swallowed.
 Causes damage to organs.
 Causes serious eye irritation.
 May cause an allergic skin reaction.
 May cause drowsiness or dizziness.
 May cause harm to breast-fed children.

Precautionary Statements:

Obtain special instructions before use.
 Do not breathe dust/fume/gas/mist/vapours/spray.
 Avoid breathing dust/fume/gas/mist/vapours/spray.
 Avoid contact during pregnancy and while nursing.
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Use only outdoors or in a well-ventilated area.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
 IF ON SKIN: Wash with plenty of water.
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 IF exposed or concerned: Call a POISON CENTER/doctor/...
 IF exposed or concerned: Get medical advice/attention.
 Call a POISON CENTER or doctor/physician if you feel unwell.
 Specific treatment (see ... on this label).
 Rinse mouth.
 If skin irritation or rash occurs: Get medical advice/attention.
 If eye irritation persists: Get medical advice/attention.
 Take off contaminated clothing and wash it before reuse.
 Store in a well-ventilated place. Keep container tightly closed.
 Store locked up.
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview:

DANGER! Toxic. This product is intended for therapeutic use only when prescribed by a physician.
 Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure:

Inhalation, Ingestion, Eye contact, Skin Absorption., Injection.

Eye:

Airborne dusts are irritating to the eyes with symptoms of burning, redness, tearing and pain

Skin:

Contact may cause irritation with symptoms of redness, rash and itching. Fentanyl can absorb through the skin; may be toxic or fatal in contact with skin.

Inhalation:

Breathing airborne dusts of this material may cause pulmonary edema, a life-threatening accumulation of fluid in the lungs.

Ingestion:

Very toxic if swallowed. May cause irritation to the mouth, throat and digestive tract.

Chronic Health Effects:

Repeated exposures to this substance may lead to psychological dependence and/or physical dependence.

Signs/Symptoms:

Symptoms of toxicity include fatigue, decreased or irregular heartbeat (cardiac depression), slow/irregular breathing (respiratory suppression), severe drowsiness and dizziness, pinpoint pupils, low blood pressure, weakness, fainting, cold clammy skin, severe nervousness, restlessness, drowsiness, dry mouth, slurred speech, headache, stupor, tremors, impaired mental and physical performance and/or coordination, euphoria, possible sensitization (allergic reaction), convulsions, unconsciousness and possibly death
Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:

Repeated exposures to this substance by inhalation, skin contact or ingestion may cause allergic hypersensitivity reactions. Pre-existing hypersensitivities to this substance or other opioid analgesics.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Fentanyl Citrate, USP	990-73-8	0.07855 mg/vial	213-588-0
Sodium Hydroxide, NF	1310-73-2	pH adjustment to 4 -7.5	215-185-5
Hydrochloric Acid, NF	7647-01-0	pH adjustment to 4 -7.5	231-595-7
Water for Injection	7732-18-5	Quantity Sufficient to 1 ml	231-791-2

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	First aid providers should avoid contact with this chemical. Wear appropriate protective equipment. For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Storage: PROTECT FROM LIGHT. Keep covered in carton until time of use. Store at 20 to 25 °C (68 to 77 °F), excursions permitted to 15 to 30 °C (59 to 86 °F). [See USP controlled room temperature].

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Eye/Face Protection: Chemical splash goggles. Wear a face shield also when splash hazard exist.

Skin Protection Description: Protective laboratory coat, apron, or disposable garment recommended.

Hand Protection Description: Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.

Respiratory Protection: No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (<http://www.cdc.gov/niosh/npptl/topics/respirators/>) for a list of respirator types and approved suppliers.

Other Protective: Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Ingredient	Guideline OSHA	Guideline ACGIH	Quebec Canada	Ontario Canada	Alberta Canada
Fentanyl Citrate, USP	Not established.	Not established.	Not established.	Not established.	Not established.
Sodium Hydroxide, NF	PEL-TWA: 2 mg/m ³	TLV-STEL: C 2 mg/m ³			
Hydrochloric Acid, NF	PEL-Ceiling/Peak: 5 ppm	TLV-STEL: C 2 ppm	VEMP-ceiling./Peak.: 5 ppm	OEL-CEV: 2 ppm	OEL-ceiling./Peak: 5 ppm
Ingredient	British Columbia Canada				
Fentanyl Citrate, USP	Not established.				
Hydrochloric Acid, NF	OEL-ceiling./Peak.: 2 ppm				

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State: Liquid.

Color: Colorless.

Odor: Odorless.

Boiling Point: Not determined.

Melting Point: Not determined.

Specific Gravity: Not determined.

Solubility: Soluble in water.

Vapor Density: Not determined.

Vapor Pressure: Not determined.

Percent Volatile: Not determined.

Evaporation Rate: Not determined.

pH: 4 - 7.5

Viscosity: Not determined.

Flash Point: Not established.

Flash Point Method: Not established.

Auto Ignition Temperature: Not established.

VOC Content: Not determined.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures.

Hazardous Polymerization: Not reported.

Conditions to Avoid: Avoid contact with extreme heat. Protect from light.

Incompatible Materials: Strong oxidizers, Acids.

Special Decomposition Products: Thermal decomposition can lead to release irritant fumes and toxic gases.

SECTION 11 : TOXICOLOGICAL INFORMATION

Fentanyl Citrate, USP :

Ingestion: Oral - Rat LD50 - Lethal dose, 50 percent kill: 18 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Sodium Hydroxide, NF :

Eye: Administration into the eye - Rabbit Standard Draize test: 400 ug [Mild]
Administration into the eye - Rabbit Standard Draize test: 1 % [Severe]
Administration into the eye - Rabbit Standard Draize test: 50 ug/24H [Severe]
Administration into the eye - Rabbit Standard Draize test: 1 mg/24H [Severe]
Administration into the eye - Rabbit Rinsed with water: 1 mg/30S [Severe] (RTECS)

Skin: Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H

Ingestion: Oral - Rabbit LDLo: 500 mg/kg [Details of toxic effects not reported other than lethal dose value]

Hydrochloric Acid, NF :

Eye: Administration into the eye - Rabbit Rinsed with water: 5 mg/30S [Mild] (RTECS)

Inhalation: Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 3124 ppm/1H [Sense Organs and Special Senses (Olfaction) - effect, not otherwise specified Sense Organs and Special Senses (Eye) - Iritis]
Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 45000 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 8300 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 60938 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 7004 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 3700 ppm/30M [Details of toxic effects not reported other than lethal dose value] (RTECS)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

DOT Hazard Class: Not Regulated.

DOT Packing Group: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Canada WHMIS: Controlled - Class: D2B Toxic

Fentanyl Citrate, USP :

EC Number: 213-588-0

Sodium Hydroxide, NF :

TSCA Inventory Status: Listed

Canada DSL: Listed

EC Number: 215-185-5

Hydrochloric Acid, NF :

TSCA Inventory Status: Listed

Section 302 EHS: EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 500

Section 313: EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical.

California PROP 65: IARC: Group 3: Unclassifiable as to carcinogenicity to humans.
Canada DSL: Listed
Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)
EC Number: 231-595-7
Water for Injection :
EC Number: 231-791-2

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 3
HMIS Fire Hazard: 0
HMIS Reactivity: 0
HMIS Personal Protection: X

SDS Creation Date: September 08, 2016
SDS Revision Date: May 16, 2019
SDS Revision Notes: Change to Section 14 - Finished product as a mixture not regulated by DOT for Transportation.

Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

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