

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Remifentanil Hydrochloride for Injection CII**
Synonyms: Remifentanil Hydrochloride for Injection
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: May 01, 2013
SDS Revision Date: November 12, 2024

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word:

WARNING.

GHS Class:

Specific Target Organ Toxicity - STOT, Single Exposure SE. Category 3.

Hazard Statements:

May cause respiratory irritation.

Precautionary Statements:

Avoid breathing dust/fume/gas/mist/vapours/spray.
 Use only outdoors or in a well-ventilated area.
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 Call a POISON CENTER or doctor/physician if you feel unwell.
 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:

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. Avoid contact with skin, eyes, nostrils and mouth.

Route of Exposure:

Inhalation Ingestion Eye contact Skin Absorption. Injection.

Eye:

Contact with eyes may cause irritation.

Skin:

May cause irritation.

Inhalation:

May cause irritation.

Ingestion:

May be harmful if ingested.

Aggravation of Pre-Existing Conditions:

None generally recognized.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Remifentanil HCl	132539-07-2	1, 2, and 5 mg/vial	
Glycine	56-40-6	15 mg/vial	
Hydrochloric Acid	7647-01-0	As needed to adjust pH	

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: 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. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

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: Store between 2 to 25°C (36 to 77°F).

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

Hydrochloric Acid :

Guideline ACGIH: TLV-STEL: 2 ppm (ceiling)

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Lyophilized powder.
Color:	White to off-white.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	2.5-3.5 (reconstituted.)
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Incompatible Materials:	Avoid contact with oxidizing agents.

SECTION 11 : TOXICOLOGICAL INFORMATION**Remifentanil HCl:**

RTECS Number:	TN2413670
Other Toxicological Information:	Intravenous. - Monkey TDLo: 0.001 mg/kg [Behavioral - Changes in psychophysiological tests] Subcutaneous - Amphibian frog TDLo: 2931661 ug/kg [Behavioral - Analgesia]

Hydrochloric Acid:

RTECS Number:	MW4025000
Eye:	Eye - Rabbit Total particulate/dust (T): 5 mg/30S (RTECS)
Skin:	Administration onto the skin - Human Standard Draize test.: 4 %/24H (RTECS)
Inhalation:	Inhalation - Rat LC50: 3124 ppm/1H [Sense Organs and Special Senses (Olfaction) - effect, not Otherwise specified Sense Organs and Special Senses (Eye) - Iritis] Inhalation - Mouse LC50: 1108 ppm/1H [Sense Organs and Special Senses (Eye) - effect, not Otherwise specified Lungs, Thorax, or Respiration - Respiratory stimulation Skin and Appendages - Dermatitis, other (After systemic exposure)] Inhalation - Rat LC50: 45000 mg/m ³ /5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 8300 mg/m ³ /30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 8300 mg/m ³ /30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - LC50: 0.1 gm/m ³ [Details of toxic effects not reported other than lethal dose value] Inhalation - Rat LC50: 60938 mg/m ³ /5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 20487 mg/m ³ /5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 7004 mg/m ³ /30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 3940 mg/m ³ /30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 3700 ppm/30M [Details of toxic effects not reported other than lethal dose value] Inhalation - Mouse LC50: 2644 ppm/30M [Details of toxic effects not reported other than lethal dose value] (RTECS)
Ingestion:	Oral - Rabbit LD50: 900 mg/kg [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.
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SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Medicine, solid, toxic, n.o.s.
DOT UN Number: UN3249
DOT Hazard Class: 6.1
DOT Packing Group: III
DOT Exemption: Limited Quantity (as a DOT Exception, not a DOT Exemption).
Quantities equal to or less than 0.25 kg per inner packaging are not subject to the full packaging and labelling requirements

IATA Shipping Name: Medicine, solid, toxic, n.o.s.
IATA UN Number: UN3249
IATA Hazard Class: 6.1
IATA Packing Group: III

SECTION 15 : REGULATORY INFORMATION

Glycine :

TSCA Inventory Status: Listed
EINECS Number: 200-711-8
Canada DSL: Listed

Hydrochloric Acid :

TSCA Inventory Status: Listed
EINECS Number: 231-595-7
SARA: EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical.
Section 302 EHS: EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 500 Lbs.
Section 304 RQ: EPCRA (SARA Title III) Section 304 Extremely Hazardous Substances (EHS) Reportable Quantities (RQ) in pounds.: 5,000 Lbs.
Canada DSL: Listed
Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 3
HMIS Fire Hazard: 1
HMIS Reactivity: 1
HMIS Personal Protection: X

SDS Creation Date: May 01, 2013

SDS Revision Date: November 12, 2024

SDS Revision Notes: Overall SDS review - no changes to formulation. Revised product name in Section 1 for accuracy by adding 'CII' (as a Controlled Substance, Schedule II), to read as 'Remifentanil Hydrochloride for Injection CII', and added synonym product name (i.e. Remifentanil Hydrochloride for Injection). Revised Section 14 - Transportation to remove reference to 'Consumer Commodity - ORM-D' and instead added 'Limited Quantity' (as a DOT Exception, not a DOT Exemption)'.
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