SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Irinotecan Hydrochloride 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:	January 15, 2011
SDS Revision Date:	June 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

Signal Word:	Not applicable.
Hazard Statements:	Not applicable.
Precautionary Statements:	Not applicable.
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.
Route of Exposure:	Inhalation, Ingestion, Eye contact, Skin Absorption., Injection.
Potential Health Effects:	
Eye:	Contact with eyes may cause irritation.
Skin:	May cause skin irritation.
Inhalation:	May cause irritation of respiratory tract.
Ingestion:	May cause irritation.
Signs/Symptoms:	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:	No medical conditions are known to be aggravated by accidental exposure.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Lactic acid	50-21-5	0.9 mg/mL	
Sorbitol-NF Powder	50-70-4	45 mg/mL	
Irinotecan Hydrochloride	100286-90-6	20 mg/mL	
Water for Injection	7732-18-5	- Quantity Sufficient. -	

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 Vigilance: (905) 770-3711.

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

Personnel 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 at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature]. Protect from light. Retain vial in carton until time of use.
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
Lactic acid	Not established.	Not established.	Not established.	Not established.	Not established.
Sorbitol-NF Powder	Not established.	Not established.	Not established.	Not established.	Not established.
Irinotecan Hydrochloride	Not established.	Not established.	Not established.	Not established.	Not established.
Water for Injection	Not established.	Not established.	Not established.	Not established.	Not established.
Ingredient	**British Columbia Canada**				
Lactic acid	Not established.				

Sorbitol-NF Powder	Not established.				
Irinotecan Hydrochloride	Not established.				
Water for Injection	Not established.				

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid.
Color:	Pale yellow.
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:	3.0 - 3.8
Molecular Formula:	Mixture
Molecular Weight:	677.19
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.
Conditions to Avoid:	Exposure to light.

SECTION 11 : TOXICOLOGICAL INFORMATION

Reproductive Toxicity:	Pregnancy Category D: Irinotecan may cause fetal harm when administered to pregnant women. Irinotecan was teratogenic in rats and rabbits. There are no adequate and well-controlled studies in pregnant women.
Lactic acid :	
Eye:	Eye - Rabbit Standard Draize test.: 750 ug (RTECS)
Skin:	Administration onto the skin - Rabbit LD50: >2 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Standard Draize test.: 5 mg/24H [severe] Administration onto the skin - Rabbit Standard Draize test.: 100 mg/24H [Moderate] Administration onto the skin - Rat TDLo: 57590 mg/kg/13W [(Intermittent) Brain and Coverings - Changes in brain weight Kidney/Ureter/Bladder - Changes in bladder weight Blood - Other changes]
Ingestion:	Oral - Rat LD50: 3543 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 4875 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Sorbitol-NF Powder :	
Ingestion:	Oral - Rat LD50: 15900 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 17800 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Other Toxicological Information:	Intravenous. - Rat LD50: 7100 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 7100 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 15 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50: 29600 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 24 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Irinotecan Hydrochloride :	
Skin:	LD50: Oral Rat 867 mg/kg LD50: Oral Rat 1026 mg/kg
Ingestion:	Oral - Rat LD50: 867 mg/kg [Sense Organs and Special Senses (Eye) - effect, not otherwise specified Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Other changes] Oral - Mouse LD50: 765 mg/kg [Tumorigenic - Active as anti-cancer agent] (RTECS)
Other Toxicological Information:	Intravenous. - Rat LD50: 83600 ug/kg [Tumorigenic - Active as anti-cancer agent] Intravenous. - Mouse LD50: 132 mg/kg [Sense Organs and Special Senses (Eye) - effect, not otherwise specified Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Other changes] Intraperitoneal. - Mouse LD50: 177 mg/kg [Tumorigenic - Active as anti-cancer agent] (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.

SECTION 15 : REGULATORY INFORMATION

Canada WHMIS:	Controlled - Class: D2B Toxic
Lactic acid :	
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.921(100)

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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

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Disclaimer:

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