SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Gemcitabine Hydrochloride for Injection, USP- 200 mg/vial**
Product Use/Restriction:	Antineoplastic.
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:	December 08, 2010
SDS Revision Date:	May 05, 2025

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:

Serious Eye Damage. category 1.
Skin corrosion. category 1.
Specific Target Organ Toxicity -STOT Repeated exposure RE. category 1 (LUNG, LIVER).
Respiratory sensitisation. category 1.
Reproductive toxicity. Category 1A.
Germ cell mutagenicity. 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:

Causes serious eye damage.
Causes severe skin burns and eye damage.
Causes damage to organs through prolonged or repeated exposure.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage fertility or the unborn child.
Suspected of causing genetic defects.
May cause an allergic skin reaction.
May cause respiratory irritation.
May cause harm to breast-fed children.

Precautionary Statements:

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
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.
In case of inadequate ventilation wear respiratory protection.
IF SWALLOWED: Rinse mouth. Do not induce vomiting.
IF ON SKIN: Wash with plenty of water.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
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: Get medical advice/attention.
Immediately call a POISON CENTER or doctor/physician.
Call a POISON CENTER or doctor/physician if you feel unwell.
Get medical advice/attention if you feel unwell.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Wash contaminated clothing 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: WARNING! Toxic. Reproductive effects. As an antineoplastic agent, this material is a suspect carcinogen. 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.

Signs/Symptoms:	Possible adverse reactions include: Myclosuppression, hepatic enzyme abnormalities, renal dysfunction, nausea, vomiting, pain, fever, rash, dyspnea, constipation, diarrhea, hemorrhage, infection, alopecia, stomatitis, somnolence, and paresthesias. Occupational exposure has not been fully investigated.
Aggravation of Pre-Existing Conditions:	Individuals with a known hypersensitivity to the drug.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Sodium Hydroxide	1310-73-2	As needed to adjust pH	
Hydrochloric acid	7647-01-0	As needed to adjust pH	
Gemcitabine (as Gemcitabine Hydrochloride)	122111-03-9	200 mg/vial	
Mannitol	69-65-8	200 mg/vial	
Sodium Acetate Trihydrate	6131-90-4	12.5 mg/vial	

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 dust. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

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 controlled room temperature 20 to 25°C (68 to 77°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 dust, 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)
Guideline OSHA:	OSHA PEL-STEL 5 ppm Ceiling/Peak
British Columbia Canada :	OEL-ceiling./Peak.: 2 ppm

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Lyophilized powder.
Color:	No information.
Odor:	No information.
Odor Threshold:	Not determined.
Boiling Point:	Not established.
Melting Point:	Not established.
Density:	No information.
Specific Gravity:	No information.
Specific Volume:	No information.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
Evaporation Rate:	No information.
pH:	Not established.
Molecular Formula:	Mixture
Molecular Weight:	299.66
Viscosity:	No information.
Coefficient of Water/Oil Distribution:	No information.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
VOC Content:	No information.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.

Hazardous Polymerization:	Not reported.
Incompatible Materials:	May react with strong oxidizing agents (peroxides, permanganates, nitric acid, etc.).

SECTION 11 : TOXICOLOGICAL INFORMATION

Teratogenicity:	Pregnancy Category D: Can cause fetal harm when administered to a pregnant woman.

Sodium Hydroxide :

RTECS Number:	WB4900000
Eye:	Corrosive to eyes.
Skin:	Corrosive to skin.
Inhalation:	Severe respiratory irritant.
Ingestion:	No data were available for acute oral toxicity.

Hydrochloric acid :

RTECS Number:	MW4025000
Eye:	Severe effects can be expected from exposure to the eyes..
Skin:	Hydrogen chloride is corrosive to the skin.
Inhalation:	Inhalation - Rat LC50: 4.2-4.7 mg/L/1hr (OECD SIDS) The irritation of hydrogen chloride to mucous is severe to workers.
Ingestion:	Oral Rat LD50 238-277 mg/kg (OECD SIDS)

Gemcitabine (as Gemcitabine Hydrochloride) :

RTECS Number:	HA3840000
Mutagenicity:	Gemcitabine was mutagenic in in vitro (mouse lymphoma assay) and in vivo (mouse micronucleus assay) mammalian test systems.
Other Toxicological Information:	Intravenous. - Rat LD50: 236 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 500 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Human TDLo: 10 mg/kg/22W (intermittent) [Behavioral - muscle weakness Gastrointestinal - nausea or vomiting Tumorigenic - active as anti-cancer agent] Intravenous. - Human TDLo: 7.5 mg/kg/2W (intermittent) [Blood - thrombocytopenia] Intravenous. - Human TDLo: 5 mg/kg/2W (intermittent) [Blood - leukopenia Blood - thrombocytopenia] Intravenous. - Human TDLo: 50 mg/kg/2W (intermittent) [Behavioral - headache Blood - thrombocytopenia Nutritional and Gross Metabolic - body temperature increase] Intravenous. - Human TDLo: 75 mg/kg/3W (intermittent) [Blood - granulocytopenia Blood - thrombocytopenia] Intravenous. - Mouse TDLo: 15 mg/kg [Reproductive - Maternal Effects - parturition Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Fertility - litter size (e.g.numberfetuses per litter; measured before birth)] Intravenous. - Mouse TDLo: 15 mg/kg [Reproductive - Maternal Effects - other effects Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death]

Mannitol :

RTECS Number:	OP2060000
Ingestion:	Oral - Rat LD50: 13500 mg/kg (RTEC)
Other Toxicological Information:	Intravenous. - Rat LD50: 9690 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 7470 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 14 gm/kg [Details of toxic effects not reported other than lethal dose value]

Sodium Acetate Trihydrate :

RTECS Number:	AJ4580000
Eye:	Mild irritation in rabbits.
Skin:	Dermal - Rabbit LD50 > 10000 mg/kg (CHEMINFO) Mild irritation in rabbits.
Inhalation:	Inhalation - Rat LC50 : >30 gm/m3/1H (RTEC)
Ingestion:	Oral - Rat LD50 : 3530 mg/kg (RTEC)
Other Toxicological Information:	Intravenous. - Mouse LDLo: 1195 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LDLo: 1300 mg/kg [Behavioral - toxic psychosis Behavioral - fluid intake Kidney/Ureter/Bladder - urine volume increased] Subcutaneous - Mouse LD50: 3200 mg/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

Sodium Hydroxide :

Ecotoxicity:	Golden orfe fish (Leuciscus idus melanotus) LC50 (48hr) 189 mg/l, Mosquitofish (Gambusia affinis) LC50 (96hr) 125 mg/l Water flea (Ceriodaphnia cf dubia) LC50 (48hr) 40 mg/l (OECD SIDS)

Hydrochloric acid :

Ecotoxicity:	Common carp (Cyprinus carpio) LC50 (96hr) 4.92 mg/L (pH 4.3) (OECD 203). Water flea (Daphnia magna) EC50 (48hr) 0.492 mg/L (pH 5.3) Green algae (Selenastrum capriornutum) EC50 (72hr) 0.492 mg/L (pH 5.3). (OECD SIDS)
Environmental Fate:	Hydrogen chloride is readily dissociated in water into hydrated protons and chloride ion.
Bioaccumulation:	No accumulation of hydrogen chloride per se in living organisms is expected due to its high solubility and dissociation properties.

Gemcitabine (as Gemcitabine Hydrochloride) :

Ecotoxicity:	No data were available for ecotoxicity.

Mannitol :

Ecotoxicity:	No data were available for ecotoxicity.

Sodium Acetate Trihydrate :

Ecotoxicity:	Zebrafish (Danio rerio) LC50 (96hr) > 100 mg/L (TS : sodium acetate) (OECD Guideline 203, GLP) Water flea (Daphnia magna) EC50 (48hr) > 919 mg/L (OECD Guideline 202, GLP) (TS : potassium acetate) Marine diatom (Skeletonema costatum) EC50 (72hr) > 1000 mg/L (TS : potassium acetate) (ECHA)
Biodegradation:	Readily biodegradable (99% after 28 days).

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

Sodium Hydroxide :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

Hydrochloric acid :

Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)

Mannitol :

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

Sodium Acetate Trihydrate :

TSCA Inventory Status:	Listed
EINECS Number:	204-823-8
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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

SDS Creation Date:	December 08, 2010
SDS Revision Date:	May 05, 2025
SDS Revision Notes:	Overall SDS review - no changes to formulation.

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