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Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Gemcitabine for Injection, USP
Product Code: 25021-208
 25021-209
Common/Trade Name: Gemcitabine Hydrochloride for Injection, Gemzar, Gemcin, Gemtro
Chemical Name: 2'-deoxy-2',2'-difluorocytidine monohydrochloride (β -isomer)
Chemical Family: Anti-tumor
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vial


Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	CAS No.
Gemcitabine Hydrochloride	48.5	122111-03-9
Mannitol	48.5	87-78-5
Sodium Acetate	3	127-09-3
Hydrochloric Acid	q.s.	7647-01-0
Sodium Hydroxide	q.s.	1310-73-2

Section 3 - Hazards Identification

Primary Physical and Health Hazards: Skin permeable. Mutagen. Irritant (eyes, skin). Reproductive and Blood effects.

Routes of Entry: Inhalation and skin absorption

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Signs & Symptoms of Exposure: Based on animal data, gemcitabine for injection may be absorbed through the skin in amounts capable of producing systemic toxicity and may be irritating to the eyes and skin. Effects of exposure due to therapeutic use may include, but are not limited to, decreased blood cell counts, nausea, vomiting, edema, rash, elevated liver enzymes, and flu-like syndrome.

Chemical Listed as Carcinogen: **NTP: No IARC: No OSHA: No**

Medical Conditions Generally Aggravated by Exposure: None known

Section 4 - First Aid Measures

Eye Exposure: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.


Skin Exposure: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Injection: See patient package insert in shipping carton for complete information..

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician.

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


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Section 5 - Fire Fighting Measures

Flash Point:	Not established
Auto-ignition Temperature:	Not established
Flammable Limits in Air:	Lower %: Not established Upper %: Not established
Flammable Limits:	Not established
Extinguishing Media:	Use water, carbon dioxide, dry chemical, foam or Halon.
Special Fire Fighting Procedures:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Unusual Fire/Explosion Hazards:	As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source. May emit toxic chloride and fluoride fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spill:	<p>Use double pairs of latex disposable gloves which must be disposed of within an hour, goggles, impermeable body covering, and approved HEPA-filtered or supplied-air respirator. If material spills occur in production area, use either wet clean-up methods, ensuring that no airborne dusts or aerosols are formed, or appropriate vacuum cleaners having high efficiency particulate air (HEPA) filters.</p> <p>It is recommended that areas handling final finished product have cytotoxic spill kits available. Spill kits should include impermeable body covering, shoe covers, latex and utility latex gloves, goggles, approved HEPA respirator, disposable dust pan and scoop, absorbent towels, spill control pillows, disposable sponges, sharps container, disposable garbage bag, and a hazardous waste label.</p>
Release to Air:	In addition to protective measures listed under "Spill", use approved HEPA filtered or supplied air respirator.
Release to Water:	Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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Section 7 - Handling and Storage

General Handling: For appropriate handling precautions in specific laboratory, manufacturing, or clinical health care operations, consult with a health and safety or technical services representative. In clinical health care settings, follow OSHA Technical Manual, Section VI, Chapter 2 - Controlling Occupational Exposure to Hazardous Drugs. This chapter covers protection of employees during cytotoxic drug preparation, administration, disposal, and the handling of human waste products potentially contaminated with cytotoxic drug substances.

GENERAL: For all work environments, wear eye protection and ELIMINATE hand-to-eye contact. Avoid skin contact, wear gloves, and take other appropriate precautions.

Waste Disposal Method: See Section 13.

Storage Conditions: Store unopened vials at 20° to 25°C (68° to 77°F); excursions between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature.] Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

Respiratory Protection: When the exposure guidelines may be exceeded, use an approved HEPA-filtered or supplied air respirator.


Eye Protection: Chemical goggles and/or face shield.

Ventilation: Extensive local exhaust, ventilated enclosure (HEPA-filtered balance enclosure, fume hood, or Class II or III vertical flow biosafety cabinet), or enclosed process equipment.

Skin Protection: For all work environments, avoid skin contact, wear gloves and take other appropriate precautions.

Other Protective Equipment: Chemical-resistant gloves and impermeable body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Additional Exposure Precautions: In production settings, airline-supplied, hood-type respirators are preferred. Shower and change clothing if skin contact occurs.

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Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Gemcitabine hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	LEG	8 hour TWA 0.3 micrograms/m ³
			12 hour TWA 0.2 micrograms/m ³

Health Based Excursions Limit: Maintain Full Shift TWA


LEG: Lilly Exposure Guidelines

Section 9 - Physical and Chemical Properties

Physical State:	Solid	Specific Gravity:	Not available
Appearance and Odor:	White to off-white , odorless	Evaporation Rate:	Not available
Boiling Point:	Not applicable	Melting Point:	Not available
Vapor Pressure:	Not available	Solubility in Water:	Soluble
Vapor Density:	Not available	pH:	2.7 to 3.3
		Molecular Weight:	299.66

Section 10 - Stability and Reactivity

Stability:	Stable at normal temperatures and pressures.
Incompatibility (Materials to avoid):	May react with strong oxidizing agents (e.g., peroxide, permanganates, nitric acid, etc.)
Hazardous Decomposition:	May emit toxic fluoride and chloride fumes when heated to decomposition.
Hazardous Polymerization:	Will not occur
Conditions to Avoid:	Not established

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Section 11 - Toxicological Information

Signs & Symptoms of Exposure:

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Acute Toxicity

Component	Type	Route	Species	Dosage
Gemcitabine hydrochloride	LD ₅₀	Oral	Rat	500 mg/kg
Gemcitabine hydrochloride	LD ₅₀	Oral	Mouse	333 mg/kg
Gemcitabine hydrochloride	LD ₅₀	Skin	Rabbit	>1000 mg/kg

Section 12 - Ecological Information

Toxicity to fish

- Gemcitabine LC50 / 96 h / Oncorhynchus mykiss (rainbow trout): > 1,043 mg/l
- LC50 / 96 h / Pimephales promelas (fathead minnow): > 1,014 mg/l

Toxicity to algae

- Gemcitabine EC50 / Selenastrum capricornutum: 5.4 mg/l
(average specific growth rate)

Toxicity to daphnia

- Gemcitabine EC50 / 48 h/ Daphnia magna (Water flea) : > 999 mg/l

Aquatic Exposure Guideline

- Gemcitabine Drinking Water: 0.045 µg/l
- Hydrochloride Chronic Exposure of Aquatic Organisms: 1.0 µg/l
- Acute Exposure of Aquatic Organisms: 5,400 µg/l

Additional ecological information

Gemcitabine hydrochloride

Dissociation constant (pKa): 3.58


Kow: 0.053, 0.053, 0.052 (pH 5, 7, 9)

Solubility (g/L): 16.0, 15.3, 15.8 (pH 5, 7, 9)

Light absorption (nm): 268 - 269

Hydrolysis: no significant hydrolysis

Aerobic biodegradation half-life: 30% in 28 days

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- Gemcitabine Additional ecological information
Gemcitabine
Microorganisms
fungus (*Chaetomium globosum*): MIC > 1000 mg/L
mold (*Aspergillus flavus*): MIC > 1000 mg/L
soil bacteria (*Comamonas acidovorans*): MIC > 1000 mg/L
N-fixing bacteria (*Azotobacter chroococcum*): MIC > 1000 mg/L
blue-green algae (*Nostoc* sp.): MIC 800 mg/L

Section 13 - Disposal Considerations

Waste Disposal: To avoid accidental exposure due to waste handling, place waste residue in a segregated, sealed plastic container. Used syringes, needles, and sharps should not be crushed, clipped, or recapped, but placed directly into an approved sharps container. Dispose of any cleanup materials and waste residue according to all applicable laws and regulations, e.g., secure chemical landfill disposal.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations


TSCA - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 – *Not on this list*

OSHA Substance Specific - *No*


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Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.
 1901 N. Roselle Rd, Suite 700
 Schaumburg, IL 60195
 847-908-1600

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)