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Section 1 - Identification

- (a) **Product Identifier:** Gemcitabine for Injection, USP
- (b) **Product Code:** 70860-204
70860-205
- Common/Trade Name:** Gemzar, Gemcin, Gemtro, Gemcitabine Hydrochloride for Injection
- Chemical Name:** 2'-deoxy-2',2'-difluorocytidine monohydrochloride (β -isomer)
- Chemical Family:** Anti-tumor
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **Classification:**
- GHS Classification:**
 Acute Oral Toxicity (Category 4)
 Eye Irritation (Category 2B)
 Toxic to Reproduction (Category 2)
 Mutagenicity (Category 2)
 Target Organ Toxicity (Category 2)
- OSHA Classification:**
 Irritant, Reproductive Toxin, Target Organ Toxin

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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):

Signal Word: Hazardous Substance, Substance hazardous to health

Hazard Statement:

- Harmful if swallowed
- Suspected of damaging fertility or the unborn child
- Suspected of causing genetic defects
- May cause damage to the skin, eyes, nervous system, blood, liver, or kidney through prolonged or repeated exposure
- Causes eye irritation

Symbols:



GHS Precautionary Statements:

Prevention


- Obtain special instructions before use
- Do not eat, drink or smoke when using this product
- Do not handle until all safety precautions have been read and understood
- Do not breathe dust/mist/vapors/spray
- Wash hands thoroughly after handling

Response

- IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
- Rinse mouth
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention
- Wash hands after handling
- IF exposed or concerned: Get medical attention/advice

Emergency Overview: Gemcitabine Injection is a solution containing gemcitabine hydrochloride, an analog of cytarabine that inhibits DNA synthesis and induces apoptosis (cell death). Clinically, gemcitabine hydrochloride is used to treat certain types of cancers. In the workplace, this material should be considered potentially irritating to the skin, eyes and respiratory tract, cytotoxic, neurotoxic, and a potential occupational reproductive hazard. Based on clinical use, possible target organs include the nervous system, blood, liver, and kidneys.

(d) Unknown Acute Toxicity N/A

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Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
2'-deoxy-2',2'-difluorocytidine monohydrochloride (β -isomer)	Gemcitabine	200 mg	95058-81-4	N/A
Sodium Acetate	Sodium Acetate	12.5 mg	127-09-3	N/A
Mannitol	Mannitol	200 mg	69-65-8	N/A


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
2'-deoxy-2',2'-difluorocytidine monohydrochloride (β -isomer)	Gemcitabine	1 gram	59277-89-3	N/A
Sodium Acetate	Sodium Acetate	62.5 mg	127-09-3	N/A
Mannitol	Mannitol	1 gram	69-65-8	N/A

*Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment.

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.

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- 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.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Use water, carbon dioxide, dry chemical, foam or Halon.
- (b) **Hazardous Combustion Products:** 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.
- (c) **Special Protective Equipment / Precautions:** Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

- Spill:** 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.
- 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.

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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.

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.

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


(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Gemcitabine Hydrochloride	OSHA	TLV	NE
	ACGIH	PEL	NE
	-----	IEG	8 hour TWA 0.3 micrograms/m ³ 12 hour TWA 0.2 micrograms/m ³

Health Based Excursions Limit: Maintain Full Shift TWA
IEG: Industry Exposure Guidelines

(b) Engineering Controls

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.


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(c) Individual Protection Measures

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.
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.

Section 9 - Physical and Chemical Properties

(a) Appearance	White to off-white lyophilized powder.
(b) Odor	Odorless
(c) Odor Threshold	Not available
(d) pH	2.7-3.3
(e) Melting Point:	>250°C
(f) Initial Boiling Point:	286-292°C
(g) Flash Point	245.7°C
(h) Evaporation Rate:	Not available
(i) Flammability	Not available
(j) Upper Lower Flammability or Explosion Limits	Not available
(k) Vapor Pressure:	Not available
(l) Vapor Density:	Not available
(m) Relative Density	Not available
(n) Solubility(ies)	Soluble in water (15.3g/L at pH 7) Slightly soluble in methanol, practically insoluble in ethanol and polar organic solvents
(o) Partition Coefficient: n-octanol/water	Not available

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(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity


(a)	Reactivity	Stable under normal conditions of use.
(b)	Chemical Stability	Stable at normal temperatures and pressures
(c)	Possibility of Hazardous Reactions	Hazardous polymerization does not occur
(d)	Conditions to Avoid	Not established
(e)	Incompatible Materials	May react with strong oxidizing agents (e.g., peroxide, permanganates, nitric acid, etc.)
(f)	Hazardous Decomposition Products	May emit toxic fluoride and chloride fumes when heated to decomposition.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation and skin absorption
(b)	Symptoms related to the physical, chemical and toxicological characteristics	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.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	None available.

(d) Acute Toxicity

Based on available data, the classification criteria are not met.

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Component	Type	Route	Species	Dosage
Gemcitabine hydrochloride	LD ₅₀	Oral	Rat	500mg/kg
		Oral	Mouse	333 mg/kg
		Skin	Rabbit	>1000 mg/kg
		Intravenous	Rat	236 mg/kg
Sodium Acetate	LD ₅₀	Oral	Rat	3530 mg/kg
		Oral	Mouse	6891 mg/kg
		Dermal	Rabbit	>10,000 mg/kg
Mannitol	LD ₅₀	Oral	Mouse	22 g/kg

(e) Hazardous Chemical Listings


NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

(a)	Ecotoxicity	<p>Not determined for product. Information for gemcitabine hydrochloride as follows:</p> <p>Toxicity to fish LC50 / 96 h / Oncorhynchus mykiss (rainbow trout): > 1,043 mg/l LC50 / 96 h / Pimephales promelas (fathead minnow): > 1,014 mg/l</p> <p>Toxicity to algae EC50 / Selenastrum capricornutum: 5.4 mg/l (average specific growth rate)</p> <p>Toxicity to daphnia EC50 / 48 h/ Daphnia magna (Water flea) : > 999 mg/l</p> <p>Aquatic Exposure Guideline Drinking Water: 0.045 µg/l Chronic Exposure of Aquatic Organisms: 1.0 µg/l Acute Exposure of Aquatic Organisms: 5,400 µg/l</p> <p>Microorganisms fungus (Chaetomium globosum): MIC > 1000 mg/L mold (Aspergillus flavus): MIC > 1000 mg/L soil bacteria (Comamonas acidovorans): MIC > 1000 mg/L</p>
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(b)	Persistence and degradability	<p>Not determined for product. Information for gemcitabine hydrochloride as follows:</p> <p>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</p>
(c)	Bioaccumulative potential	The relatively low partition coefficient (log KOW = -1.3) indicates a low potential for bioaccumulation
(d)	Mobility in soil	Not available
(e)	Other Adverse Effects	<p>Based on the moderate water solubility, it is expected to be mobile and possibly enter groundwater.</p> <p>Due to its moderate water solubility, it is expected to migrate from land to water. It is not expected to partition to sediment and wastewater solids.</p>

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 per all applicable laws and regulations, e.g., secure chemical landfill disposal.

Section 14 - Transport Information


Not regulated for transport under USDOT, IATA, or IMDG regulations.

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division 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 – Not regulated
- CERCLA - Not on this list
- SARA 302 - Not on this list
- SARA 313 - Not on this list

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Section 16 - Other Information


As of the date of effectiveness, 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 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:

Athenex Pharmaceutical Division
10 N. Martingale Road, Suite 230
Schaumburg, IL 60173
847-886-9515

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

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
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

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NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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
SDS	Safety Data Sheet
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)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS015

Revision: 03

Title: Gemcitabine for Injection, USP

All dates and times are in Eastern Standard Time.

SDS Review

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	Director of Corporate Quality		
Michael Spengler (MSPENGLER)	QC Applications Specialist		
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Emily Means (EMEANS)	QA Document Specialist	26 Nov 2019, 07:26:14 AM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	13 Apr 2020, 10:21:51 AM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	13 Apr 2020, 11:55:02 AM	Approved