

SAFETY DATA SHEET

1. Identification

Product identifier	Gemzar	
Other means of identification		
Item Code	VL7502, VL7501	
Synonyms	Cytidine, 2'-deoxy-2',2'-difluoro-, monohydrochloride * 2'-Deoxy-2',2'-difluorocytidine monohydrochloride (beta-isomer)	
Recommended use	Pharmaceutical	
Recommended restrictions	None known.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	Eli Lilly and Company	
Address	Lilly Corporate Center Indianapolis, IN 46285 United States	
Telephone	Phone:	+1-317-276-2000
E-mail	lilly_msds@lilly.com	
Emergency phone number	CHEMTREC:	+1-800-424-9300

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Acute toxicity, dermal	Category 4
	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Germ cell mutagenicity	Category 2
	Reproductive toxicity	Category 1B
	Specific target organ toxicity, repeated exposure	Category 1
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger	
Hazard statement		
H302	Harmful if swallowed.	
H312	Harmful in contact with skin.	
H315	Causes skin irritation.	
H320	Causes eye irritation.	
H341	Suspected of causing genetic defects.	
H360	May damage fertility or the unborn child.	
H372	Causes damage to organs through prolonged or repeated exposure.	
Precautionary statement		
Prevention		
P201	Obtain special instructions before use.	
P202	Do not handle until all safety precautions have been read and understood.	
P280	Wear protective gloves/protective clothing.	
Response		
P308 + P313	IF exposed or concerned: Get medical advice/attention.	
Storage	Not available.	

Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Gemcitabine Hydrochloride	CYTIDINE, 2'-DEOXY-2',2'-DIFLUORO-, HYDROCHLORIDE (1:1)	122111-03-9	51 - 53
Excipients		NA	47 - 49

4. First-aid measures

Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. Get medical attention immediately.
Skin contact	Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Call a POISON CENTER or doctor/physician if you feel unwell. Wash contaminated clothing before reuse.
Eye contact	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
Ingestion	Give several glasses of water. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician or poison control center immediately.
Most important symptoms/effects, acute and delayed	May cause eye irritation. May cause skin irritation. May cause reproductive effects. Suspected of causing genetic defects. Risk of damage to blood system.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. Fire-fighting measures

Suitable extinguishing media	Water. Carbon dioxide (CO2). Dry chemical.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	May emit toxic chloride and fluoride fumes when heated to decomposition.
Special protective equipment and precautions for firefighters	Wear self-contained breathing apparatus and protective clothing.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Avoid inhalation of dust. See Section 8 of the SDS for Personal Protective Equipment.
Methods and materials for containment and cleaning up	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.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Avoid discharge into water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Wear personal protective equipment. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

Occupational exposure limits

Lilly (LEG) Components

Components	Type	Value
Gemcitabine Hydrochloride (CAS 122111-03-9)	TWA (12hrs)	0.2 ug/m3
	TWA (8hrs)	0.3 ug/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

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

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear goggles/face shield.

Skin protection

Hand protection

Chemical-resistant gloves and impermeable body covering to minimize skin contact.

Other

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.

Respiratory protection

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

Thermal hazards

Not available.

General hygiene considerations

GENERAL: For all work environments, wear eye protection, avoid skin contact, wear gloves, and take other appropriate precautions.

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.

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

9. Physical and chemical properties

Appearance

Dessicated solid in vial

Physical state

Solid.

Form

Lyophilized cake.

Color

White to Off-white.

Odor

None known.

Odor threshold

No data available.

pH

Acidic

Melting point/freezing point

Not available.

Initial boiling point and boiling range

No data available.

Flash point

No data available.

Evaporation rate

No data available.

Flammability (solid, gas)

No test data available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) No data available.

Flammability limit - upper (%) No data available.

Explosive limit - lower (%) No data available.

Explosive limit - upper (%) No data available.

Vapor pressure

No data available.

Vapor density

No data available.

Relative density

No data available.

Solubility(ies)	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	No data available.
Decomposition temperature	No data available.
Viscosity	No data available.
Other information	
Density	No data available.
Explosive properties	Not explosive
Oxidizing properties	No oxidizing properties.
Potential for dust explosion	No data available.

10. Stability and reactivity

Reactivity	Not water reactive.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Excessive heat.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	May emit toxic chloride and fluoride fumes when heated to decomposition.

11. Toxicological information

Information on toxicological effects

Acute toxicity Harmful if absorbed through skin or swallowed. May be harmful if swallowed. May be harmful if absorbed through skin.

Product	Species	Test Results
Gemzar (CAS Mixture)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	> 1000 mg/kg Mortality

Components	Species	Test Results
Gemcitabine Hydrochloride (CAS 122111-03-9)		
Acute		
<i>Dermal</i>		
LD50	Rabbit	205 - 1000 mg/kg
<i>Oral</i>		
LD	Mouse	333 mg/kg Mortality
	Rat	> 500 mg/kg

Skin corrosion/irritation Rabbit, Irritating.

Serious eye damage/eye irritation Rabbit, Irritating. (Gemcitabine Hydrochloride)

Respiratory or skin sensitization

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Did not cause sensitization on laboratory animals. (Gemcitabine Hydrochloride)

Germ cell mutagenicity Mutagenic in mouse lymphoma assay and mouse micronucleus test. Not mutagenic in bacterial cells and other mammalian cell tests. (Gemcitabine Hydrochloride)

Carcinogenicity No carcinogenicity data available for this product. Not listed by ACGIH, IARC, NIOSH, NTP OR OSHA.
Due to lack of data the classification is not possible.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Decreased sperm formation and decreased fertility in males, and reproductive tissue changes. Depressed fetal viability and weight and malformations at doses toxic to the mother. (Gemcitabine Hydrochloride)

Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Animal studies have reported the following effects: Blood effects (decreased red blood cell, white blood cell, and platelet counts). (Gemcitabine Hydrochloride)
Aspiration hazard	Not applicable.
Chronic effects	Animal studies have reported the following effects: Blood effects (decreased red blood cell, white blood cell, and platelet counts). (Gemcitabine Hydrochloride)
Further information	Effects reported with therapeutic administration: Blood effects (decreased red blood cell, white blood cell, and platelet counts). Nausea, vomiting. Rash. Liver effects.

12. Ecological information

Ecotoxicity Toxic to aquatic life with long lasting effects.

Lilly Aquatic Exposure Guideline: Drinking Water: 0.045 µg/l
Lilly Aquatic Exposure Guideline: Acute Exposure of Aquatic Organisms: 5400 µg/l
Lilly Aquatic Exposure Guideline: Chronic Exposure of Aquatic Organisms: 1.0 µg/l

Components	Species	Test Results
Gemcitabine Hydrochloride (CAS 122111-03-9)		
	IC50	Bacteria (n-fixing) (Azotobacter chroococcum) > 1000 mg/l
		Bacteria (soil) > 1000 mg/l
		Fungus > 1000 mg/l
		Mold > 1000 mg/l
<i>Acute</i>		
Crustacea	EC50	Daphnia magna > 999 mg/l, 48 h
Other	EC50	Selenastrum capricornutum (new name Pseudokirchnerella subca 5.4 mg/l (average specific growth rate)
	LC50	Rainbow Trout > 1043 mg/l, 96 h
Aquatic		
Algae	IC50	Blue-green algae (Spirulina platensis) 800 mg/l
<i>Acute</i>		
Fish	LC50	Fathead minnow (Pimephales promelas) > 1014 mg/l, 96 h
Persistence and degradability	Aerobic biodegradation half-life: 30% in 28 days (Gemcitabine Hydrochloride) Hydrolysis: no significant hydrolysis (Gemcitabine Hydrochloride)	
Bioaccumulative potential	log Kow: < 4. (Gemcitabine Hydrochloride)	
Partition coefficient n-octanol / water (log Kow)		
Gemcitabine Hydrochloride		0.052, (pH 9)
		0.053, (pH 5)
		0.053, (pH 7)

Mobility in soil No data available.

Other adverse effects None known.

13. Disposal considerations

Disposal instructions 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.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Gemcitabine Hydrochloride)
Transport hazard class(es)
Class 9
Subsidiary risk -

Packing group	III
Environmental hazards	Yes
ERG Code	9L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

IMDG

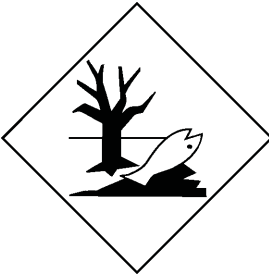
UN number	UN3077
UN proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Gemcitabine Hydrochloride)
Transport hazard class(es)	
Class	9
Subsidiary risk	-
Packing group	III
Environmental hazards	
Marine pollutant	Yes
EmS	F-A, S-F
Special precautions for user	Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code This substance/mixture is not intended to be transported in bulk.

IATA; IMDG



Marine pollutant



15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
CERCLA/SARA Hazardous Substances - Not applicable.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 04-10-2014

Revision date 06-10-2014

Version # 02

Lilly Lab Code
Health: 2
Fire: 1
Reactivity: 0
Special 1: R

Disclaimer
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 MERCHANT ABILITY 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:
Eli Lilly and Company
Hazard Communication
+1-317-651-9533

Revision Information
Hazard(s) identification: Hazard statement
Toxicological Information: Toxicological Data
Regulatory Information: Risk Phrases - Class.
GHS: Qualifiers