



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)
LY Number	LY188011
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 (Blood)
OSHA defined hazards	Combustible dust	

Label elements



Signal word Danger

Hazard statement

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious 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) LY188011 Hydrochloride	122111-03-9	51 - 53

Composition comments Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

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	Causes skin irritation. Causes serious eye 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

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. Use an approved respirator. Select respirator with appropriate protection factor. Select appropriate respirator for physical characteristics of material.

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 in contact with skin. Harmful if swallowed.

Product	Species	Test Results
Gemzar®		
Acute		
Dermal		
LD50	Rabbit	> 1000 mg/kg Mortality
Components		
Species		
Test Results		
Gemcitabine Hydrochloride (CAS 122111-03-9)		
Acute		
Dermal		
LD50	Rabbit	205 - 1000 mg/kg
Oral		
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.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

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.

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>		
Other	EC50	Pseudokirchnerella subcapitata 5.4 mg/l (average specific growth rate)
Aquatic		
Algae	IC50	Blue-green algae (Spirulina platensis) 800 mg/l
<i>Acute</i>		
Crustacea	EC50	Daphnia magna > 999 mg/l, 48 h
Fish	LC50	Fathead minnow (Pimephales promelas) > 1014 mg/l, 96 h
		Rainbow Trout > 1043 mg/l, 96 h

LILLY AQUATIC EXPOSURE GUIDELINES:

Gemcitabine Hydrochloride

Acute LAEG (at the edge of the acute mixing zone): 5400 µg/l
 Chronic LAEG (at the edge of the chronic mixing zone): 1 µg/l
 Drinking water LAEG (at the point where surface water is taken for drinking water): 0.045 µg/l

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.

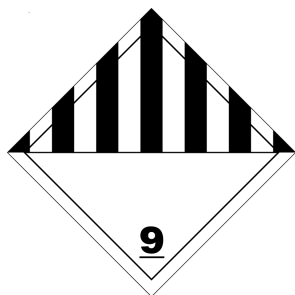
IATA

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 with restrictions.
Cargo aircraft only	Allowed with restrictions.

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	Not available.

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.

Toxic Substances Control Act (TSCA)

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 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Classified hazard categories

Combustible dust
Acute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation
Germ cell mutagenicity
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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.

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 11-21-2014

Revision date 02-20-2019

Version # 03

List of abbreviations LEG: Lilly Exposure Guideline.
TWA: Time Weighted Average

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