

GEMCITABINE INJECTION 100 mg/mL

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 09/13/2017 Date of Issue: 09/13/2017

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: GEMCITABINE INJECTION 100 mg/mL

1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutical

1.3. Name, Address, and Telephone of the Responsible Party

Company

Accord Healthcare, Inc.

1009 Slater Road

Suite 210-B

Durham, NC 27703

USA

Telephone: 1-919-941-7880

Fax- 1-919-941-7881

www.accord-healthcare.com

1.4. Emergency Telephone Number

Emergency Number : 1-800-424-9300
Call CHEMTREC Day or Night

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Flam. Liq. 2	H225
Skin Irrit. 2	H315
Eye Irrit. 2	H319
Muta. 1B	H340
Carc. 2	H351
Repr. 1B	H360
STOT SE 3	H335
STOT RE 1	H372
Aquatic Chronic 3	H412

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)

:



GHS02



GHS07



GHS08

Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: H225 - Highly flammable liquid and vapor.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.
H340 - May cause genetic defects.
H351 - Suspected of causing cancer.
H360 - May damage fertility or the unborn child.
H372 - Causes damage to organs through prolonged or repeated exposure.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary Statements (GHS-US)

: P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P210 - Keep away from extremely high or low temperatures, ignition sources, and incompatible materials. - No smoking.
P240 - Ground/Bond container and receiving equipment.
P241 - Use explosion-proof electrical, ventilating, and lighting equipment.

GEMCITABINE INJECTION 100 mg/mL

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

P242 - Use only non-sparking tools.
P243 - Take precautionary measures against static discharge.
P260 - Do not breathe vapors, mist, or spray.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P271 - Use only outdoors or in a well-ventilated area.
P273 - Avoid release to the environment.
P280 - Wear protective gloves, protective clothing, and eye protection.
P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P312 - Call a poison center or doctor if you feel unwell.
P314 - Get medical advice/attention if you feel unwell.
P321 - Specific treatment (see section 4 on this SDS).
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P370+P378 - In case of fire: Use appropriate media (see section 5) to extinguish.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.
P403+P233+P235 - Store in a well-ventilated place. Keep container tightly closed. Keep cool.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Ethyl alcohol	(CAS No) 64-17-5	45.25 - 45.43	Flam. Liq. 2, H225 Eye Irrit. 2A, H319
Polyethylene glycol	(CAS No) 25322-68-3	25.72	STOT SE 3, H335
1,2-Propanediol	(CAS No) 57-55-6	15.43	Not classified
Gemcitabine hydrochloride	(CAS No) 122111-03-9	11.71	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Muta. 1B, H340 Carc. 2, H351 Repr. 1B, H360 STOT RE 1, H372 Aquatic Chronic 2, H411
Sodium hydroxide	(CAS No) 1310-73-2	Used to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

GEMCITABINE INJECTION 100 mg/mL

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Hydrochloric acid	(CAS No) 7647-01-0	Used to adjust pH	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
-------------------	--------------------	-------------------	---

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Causes serious eye irritation. Causes skin irritation. May cause respiratory irritation. May cause genetic defects. Suspected of causing cancer. May damage fertility. May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

Symptoms/Injuries After Inhalation: Irritation of the respiratory tract and the other mucous membranes.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: May cause genetic defects. Suspected of causing cancer. May damage fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂). Water may be ineffective but water should be used to keep fire-exposed container cool.

Unsuitable Extinguishing Media: Do not use a heavy water stream. A heavy water stream may spread burning liquid.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Highly flammable liquid and vapor.

Explosion Hazard: May form flammable or explosive vapor-air mixture.

Reactivity: Reacts violently with strong oxidizers. Increased risk of fire or explosion.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers. In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen chloride gas. Hydrogen Fluoride (HF).

Other Information: Do not allow run-off from fire fighting to enter drains or water courses.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not get in eyes, on skin, or on clothing. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. Use special care to avoid static electric charges. Do not breathe vapor, mist or spray.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel. Stop leak if safe to do so.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

GEMCITABINE INJECTION 100 mg/mL

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Emergency Procedures: Ventilate area. Eliminate ignition sources. Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

6.2. Environmental Precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. As an immediate precautionary measure, isolate spill or leak area in all directions.

Methods for Cleaning Up: Absorb and/or contain spill with inert material. Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Do not take up in combustible material such as: saw dust or cellulosic material. Use only non-sparking tools. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Handle empty containers with care because residual vapors are flammable.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Take precautionary measures against static discharge. Use only non-sparking tools. Do not breathe vapors, mist, spray. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes, on skin, or on clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations. Take action to prevent static discharges. Ground and bond container and receiving equipment. Use explosion-proof electrical, ventilating, and lighting equipment.

Storage Conditions: Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store in a well-ventilated place. Keep container tightly closed. Keep in fireproof place.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Polyethylene glycol (25322-68-3)		
USA AIHA	WEEL TWA (mg/m ³)	10 mg/m ³ (MW>200-aerosol)
1,2-Propanediol (57-55-6)		
USA AIHA	WEEL TWA (mg/m ³)	10 mg/m ³
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH Ceiling (ppm)	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
USA IDLH	US IDLH (ppm)	50 ppm
USA OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
USA OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm
Ethyl alcohol (64-17-5)		
USA ACGIH	ACGIH STEL (ppm)	1000 ppm
USA ACGIH	ACGIH chemical category	Confirmed Animal Carcinogen with Unknown Relevance to Humans
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1900 mg/m ³

GEMCITABINE INJECTION 100 mg/mL

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

USA NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm
USA IDLH	US IDLH (ppm)	3300 ppm (10% LEL)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1900 mg/m ³
USA OSHA	OSHA PEL (TWA) (ppm)	1000 ppm

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Gas detectors should be used when flammable gases or vapors may be released. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics. Wear fire/flamm resistant/retardant clothing.

Hand Protection

: Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Appearance	: No data available
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Reacts violently with strong oxidizers. Increased risk of fire or explosion.

10.2. Chemical Stability: Extremely flammable liquid and vapor. May form flammable or explosive vapor-air mixture.

10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.

GEMCITABINE INJECTION 100 mg/mL

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, heat, hot surfaces, sparks, open flames, incompatible materials, and other ignition sources.

10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products: None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Polyethylene glycol (25322-68-3)	
LD50 Oral Rat	22 g/kg
LD50 Dermal Rabbit	> 20 ml/kg
1,2-Propanediol (57-55-6)	
LD50 Oral Rat	20 g/kg
LD50 Dermal Rabbit	20800 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 Dermal Rabbit	> 5010 mg/kg
Ethyl alcohol (64-17-5)	
LD50 Oral Rat	10470 mg/kg
LD50 Dermal Rat	20 ml/kg
LC50 Inhalation Rat	124.7 mg/l/4h
Gemcitabine hydrochloride (122111-03-9)	
ATE (Oral)	500.00 mg/kg body weight
ATE (Dermal)	1,100.00 mg/kg body weight

Skin Corrosion/Irritation: Causes skin irritation.

Serious Eye Damage/Irritation: Causes serious eye irritation.

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: May cause genetic defects.

Carcinogenicity: Suspected of causing cancer.

Hydrochloric acid (7647-01-0)	
IARC group	3
Ethyl alcohol (64-17-5)	
IARC group	1
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: May damage fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): May cause respiratory irritation.

Specific Target Organ Toxicity (Repeated Exposure): Causes damage to organs through prolonged or repeated exposure.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Irritation of the respiratory tract and the other mucous membranes.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: May cause genetic defects. Suspected of causing cancer. May damage fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Harmful to aquatic life with long lasting effects.

1,2-Propanediol (57-55-6)	
LC50 Fish 1	51600 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	10000 mg/l (Exposure time: 24 h - Species: Daphnia magna)
LC50 Fish 2	41 - 47 ml/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 2	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l

GEMCITABINE INJECTION 100 mg/mL

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)
Ethyl alcohol (64-17-5)	
EC50 Daphnia 1	9268 - 14221 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	> 100 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
ErC50 (Algae)	1000 mg/l

12.2. Persistence and Degradability

GEMCITABINE INJECTION 100 mg/mL	
Persistence and Degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative Potential

GEMCITABINE INJECTION 100 mg/mL	
Bioaccumulative Potential	Not established.

1,2-Propanediol (57-55-6)	
BCF Fish 1	< 1
Log Pow	-0.92
Ethyl alcohol (64-17-5)	
Log Pow	-0.32

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Handle empty containers with care because residual vapors are flammable.

Ecology - Waste Materials: Avoid release to the environment. This material is hazardous to the aquatic environment. Keep out of sewers and waterways.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Proper Shipping Name : ETHANOL SOLUTIONS
Hazard Class : 3
Identification Number : UN1170
Label Codes : 3
Packing Group : II
ERG Number : 127



14.2. In Accordance with IMDG

Proper Shipping Name : ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Hazard Class : 3
Identification Number : UN1170
Packing Group : II
Label Codes : 3
EmS-No. (Fire) : F-E
EmS-No. (Spillage) : S-D



14.3. In Accordance with IATA

Proper Shipping Name : ETHANOL SOLUTION
Packing Group : II
Identification Number : UN1170
Hazard Class : 3
Label Codes : 3
ERG Code (IATA) : 3L



GEMCITABINE INJECTION 100 mg/mL

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

GEMCITABINE INJECTION 100 mg/mL	
SARA Section 311/312 Hazard Classes	Fire hazard Immediate (acute) health hazard Delayed (chronic) health hazard
Polyethylene glycol (25322-68-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Inventory Update Reporting Rule, i.e, Partial Updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 710(C)).
1,2-Propanediol (57-55-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	1000 lb
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
Ethyl alcohol (64-17-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Ethyl alcohol (64-17-5)	
U.S. - California - Proposition 65 - Carcinogens List	WARNING: This product contains chemicals known to the State of California to cause cancer. Ethyl Alcohol is included on the Proposition 65 list when it is used in alcoholic beverages.
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects. Ethyl Alcohol is included on the Proposition 65 list when it is used in alcoholic beverages.
1,2-Propanediol (57-55-6)	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Sodium hydroxide (1310-73-2)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Hydrochloric acid (7647-01-0)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List	
U.S. - Pennsylvania - RTK (Right to Know) List	
Ethyl alcohol (64-17-5)	
U.S. - Massachusetts - Right To Know List	
U.S. - New Jersey - Right to Know Hazardous Substance List	
U.S. - Pennsylvania - RTK (Right to Know) List	

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 09/13/2017

GEMCITABINE INJECTION 100 mg/mL

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Other Information

: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Carc. 2	Carcinogenicity Category 2
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2	Serious eye damage/eye irritation Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 2	Flammable liquids Category 2
Met. Corr. 1	Corrosive to metals Category 1
Muta. 1B	Germ cell mutagenicity Category 1B
Repr. 1B	Reproductive toxicity Category 1B
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H225	Highly flammable liquid and vapor
H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H340	May cause genetic defects
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child
H372	Causes damage to organs through prolonged or repeated exposure
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H411	Toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)