



SAFETY DATA SHEET

Revision date 16-Jun-2025

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Gemcitabine (gemcitabine hydrochloride) for Injection (Hospira, Inc.)
Product Code(s) PZ03241
Synonyms Gemcitabine for Injection, USP (Lyophilized)
Trade Name: Not applicable
Chemical Family: Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as Antineoplastic

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

Acute toxicity - Oral	Category 4 - (H302)
Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2A - (H319)
Germ cell mutagenicity	Category 1B - (H340)
Reproductive toxicity	Category 1B - (H360FD)

OSHA Classification

Physical Hazard Combustible Dust

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements

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Signal word

Hazard statements

Danger

H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H360FD - May damage fertility. May damage the unborn child
H340 - May cause genetic defects
OSHA - May form combustible dust concentrations in air

Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P270 - Do not eat, drink or smoke when using this product
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P264 - Wash hands thoroughly after handling
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash it before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

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3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Gemcitabine hydrochloride (CAS #: 122111-03-9)	45-55		Not Listed	Acute Tox. 4 (H302) Eye Irrit. 2B (H319) Skin Irrit. 2 (H315) Repr. 1B (H360FD) Muta. 1B (H340)	Not classified	No data available	No data available
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr. 1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Sodium acetate trihydrate (CAS #: 6131-90-4)	*		Not Listed	Not classified	Not classified	No data available	No data available
Mannitol (CAS #: 69-65-8)	*	-	200-711-8	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
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Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Gemcitabine hydrochloride 122111-03-9	>500	No data available	No data available	No data available	No data available
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
Mannitol 69-65-8	13500	No data available	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

* Proprietary

** to adjust pH

+ Substance with a Union workplace exposure limit

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2, alcohol-resistant foam or water spray.
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5.2. Special hazards arising from the substance or mixture

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Specific hazards arising from the chemical Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Restrict access to work area. Minimize dust generation and accumulation. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

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Specific use(s)

Pharmaceutical drug product. Antineoplastic.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Gemcitabine hydrochloride

Pfizer OEL TWA-8 Hr: 0.05 µg/m³

Sodium hydroxide

ACGIH OEL (Ceiling)

2 mg/m³

ACGIH TLV

Ceiling: 2 mg/m³

Austria

TWA-TMW: 2 mg/m³; inhalable fraction

STEL-KZGW: 4 mg/m³ (8 X 5 min); inhalable fraction

Bulgaria

TWA: 2.0 mg/m³; alkaline aerosols

Czech Republic

1 mg/m³

Ceiling: 2 mg/m³

Denmark

Ceiling: 2 mg/m³;

Estonia

TWA: 1 mg/m³;

STEL: 2 mg/m³;

Finland

Ceiling: 2 mg/m³;

France

2 mg/m³

Hungary

TWA-AK: 1 mg/m³;

STEL-CK: 2 mg/m³;

Ireland

STEL: 2 mg/m³;

Ceiling Limit Value

2 mg/m³

Latvia

TWA: 0.5 mg/m³;

Poland

TWA-NDS: 0.5 mg/m³;

STEL-NDSch: 1 mg/m³;

Romania

TWA: 1 mg/m³;

STEL: 3 mg/m³;

Slovakia

TWA: 2 mg/m³;

Spain

STEL (VLA-EC): 2 mg/m³;

Switzerland

TWA-MAK: 2 mg/m³; inhalable dust

STEL-KZGW: 2 mg/m³; inhalable dust

OSHA PEL

TWA: 2 mg/m³

(vacated) Ceiling: 2 mg/m³

STEL: 2 mg/m³;

United Kingdom

Mannitol

Russia

MAC: 10 mg/m³

+ Hydrochloric Acid

ACGIH OEL (Ceiling)

2 ppm

ACGIH TLV

Ceiling: 2 ppm

Austria

TWA-TMW: 5 ppm;

TWA-TMW: 8 mg/m³;

STEL-KZGW: 10 ppm (8 X 5 min);

STEL-KZGW: 15 mg/m³ (8 X 5 min);

Bulgaria

TWA: 5 ppm;

TWA: 8.0 mg/m³;

STEL: 10 ppm;

STEL: 15.0 mg/m³;

Czech Republic

8 mg/m³

Ceiling: 15 mg/m³

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Denmark	STEL: 5 ppm; STEL: 8 mg/m ³ ;
Estonia	TWA: 5 ppm; TWA: 8 mg/m ³ ;
European Union	STEL: 10 ppm; STEL: 15 mg/m ³ ;
Finland	TWA: 5 ppm; TWA: 8 mg/m ³ ;
Germany DFG	STEL: 10 ppm; STEL: 15 mg/m ³ ;
Germany TRGS	STEL: 5 ppm; STEL: 7.6 mg/m ³ ;
Hungary	TWA-MAK: 2 ppm; I(2); TWA-MAK: 3.0 mg/m ³ ; I(2); Peak: 4 ppm; Peak: 6 mg/m ³ ;
Ireland	TWA-AGW; 2 ppm (exposure factor 2); TWA-AGW; 3 mg/m ³ (exposure factor 2); TWA-AK: 8 mg/m ³ ;
Italy MDLPS	TWA-AK: 5 ppm; STEL-CK: 165 mg/m ³ ;
Ceiling Limit Value	STEL-CK: 10 ppm; TWA: 8 mg/m ³ ;
Latvia	TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Netherlands	TWA: 5 ppm; TWA: 8 mg/m ³ ;
Poland	STEL: 10 ppm; STEL: 15 mg/m ³ ;
Romania	TWA: 5 ppm; TWA: 8 mg/m ³ ;
Russia	STEL: 10 ppm; STEL: 15 mg/m ³ ;
Slovakia	MAC: 5 mg/m ³ ; TWA: 5 ppm; TWA: 8.0 mg/m ³ ;
Spain	Ceiling: 15 mg/m ³ ; TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m ³ ;
Switzerland	STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m ³ ;
	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m ³ ; STEL-KZGW: 4 ppm;

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U.S. - OSHA - Final PELs - Ceiling Limits	STEL-KZGW: 6 mg/m ³ ; 5 ppm 7 mg/m ³
OSHA PEL	Ceiling: 5 ppm Ceiling: 7 mg/m ³ (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m ³
United Kingdom	TWA: 1 ppm; gas and aerosol mist TWA: 2 mg/m ³ ; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m ³ ; gas and aerosol mist

8.2. Exposure controls

Engineering controls

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section. It is recommended that all operations be fully enclosed and no air recirculated.

Personal protective equipment

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Eye/face protection

Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Hand protection

Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).

Skin and body protection

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

Respiratory protection

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).

Thermal hazards

No information available.

Environmental exposure controls

No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

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Appearance	Lyophilized powder
Physical state	Powder
Color	White to off-white
Odor	No information available.
Odor threshold	No information available

Property

Melting point / freezing point
Boiling point or initial boiling point and boiling range
Flammability (solid, gas)
Lower and upper explosion limit/flammability limit
 Lower explosion limit
 Upper explosion limit
Flash point
Autoignition temperature
Decomposition temperature
 SADT (°C)
pH
 pH (as aqueous solution)
Kinematic viscosity
 Dynamic viscosity
Solubility
Vapor pressure
Density and/or relative density
 Bulk density
 Liquid Density
Vapor density
Particle characteristics
 Particle Size
 Particle Size Distribution

Values

No data available
No data available
No data available
No data available
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No data available
No information available
No information available

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

9.2.1. Information with regard to physical hazard classes
No information available

9.2.2. Other safety characteristics
No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

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Conditions to avoid

Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials

As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:

The information included in this section describes the potential hazards of the individual ingredients

Short term

May be absorbed through the skin and cause systemic effects.

Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system and blood and blood forming organs Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects:

Adverse effects associated with therapeutic use include decreased blood cell count, nausea, vomiting, swelling, skin rash, liver enzyme changes, flu-like syndrome.

Acute toxicity

Classification is based on mixture calculation methods based on component data

Serious eye damage/eye irritation

Classification is based on mixture calculation methods based on component data.

Skin corrosion/irritation

Classification is based on mixture calculation methods based on component data.

Respiratory or skin sensitization

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

STOT - single exposure

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

STOT - repeated exposure

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

Reproductive toxicity

Classification is based on mixture calculation methods based on component data.

Germ cell mutagenicity

Classification is based on mixture calculation methods based on component data.

Carcinogenicity

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

Aspiration hazard

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

Acute Toxicity: (Species, Route, End Point, Dose)

Gemcitabine hydrochloride

Mouse Oral Minimum Lethal Dose 333 mg/kg

Rat Oral LD50 > 500 mg/kg

Rabbit Dermal LD50 > 1000 mg/kg

Mannitol

Rat Oral LD 50 13500 mg/kg

Mouse Oral LD 50 22 g/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
Mannitol	= 13500 mg/kg (Rat)	-	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

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Skin irritation Rabbit Irritant
Eye irritation Rabbit Irritant
+ Hydrochloric Acid
Skin irritation Severe
Eye irritation Severe
Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Gemcitabine hydrochloride

6 Month(s) Dog No route specified 0.04 mg/kg/day NOEL Blood, Erythroid cells, Lymphoid tissue, Immune system
6 Month(s) Mouse No route specified 0.006 mg/kg/day LOEL Erythroid cells, Male reproductive system, Spleen

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Gemcitabine hydrochloride

Reproductive & Fertility Mouse Intraperitoneal 0.05 mg/kg/day NOEL Fertility
Fertility and Embryonic Development Mouse Intravenous 0.25 mg/kg/day LOEL Fetotoxicity, Embryotoxicity, Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Gemcitabine hydrochloride

In Vivo Micronucleus Mouse Positive
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Positive
Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vivo Sister Chromatid Exchange Negative
In Vitro Chromosome Aberration Negative

+ Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

+ Hydrochloric Acid

IARC Group 3

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

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

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Gemcitabine hydrochloride

Oncorhynchus mykiss (Rainbow Trout) LC50 96 hours > 1043 mg/L
Pimephales promelas (Fathead Minnow) LC50 96 > 1014 mg/L

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Daphnia Magna (Water Flea) EC50 48 hours > 999 mg/L
Selenastrum capricornutum (Green Alga) EC50 5.4 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Gemcitabine hydrochloride

Nostoc sp. (Freshwater Cyanobacteria) MIC 800 mg/L
Aspergillus niger (Fungus) MIC > 1000 mg/L

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

UN number: Not applicable
UN proper shipping name: Not applicable
Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Gemcitabine hydrochloride	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
Sodium acetate trihydrate	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
AICS	Present
Sodium hydroxide	
CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6
Mannitol	
CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-711-8
AICS	Present
+ Hydrochloric Acid	
CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-595-7
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5 Schedule 6

National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

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TRGS 905

Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

Major Accidents Ordinance SR 814.012 Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide 1310-73-2	75	-
+ Hydrochloric Acid 7647-01-0	75	-

Persistent Organic Pollutants

Not applicable

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid 7647-01-0	25	250

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

SAFETY DATA SHEET

Product Name Gemcitabine (gemcitabine hydrochloride) for Injection
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NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H315 - Causes skin irritation H340 - May cause genetic defects H360FD - May damage fertility. May damage the unborn child H319 - Causes serious eye irritation H314 - Causes severe skin burns and eye damage H331 - Toxic if inhaled

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Added Pfizer OEL (Section 8). Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

Revision date 16-Jun-2025

Prepared By Pfizer Global Environment, Health, and Safety

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