

Gemcitabine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 03/04/2023 Revision date: 15/05/2025 Supersedes version of: 03/04/2023 Version: 2.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
Substance name : Gemcitabine hydrochloride
Chemical name : Gemcitabine hydrochloride
CAS-No. : 122111-03-9
Product code : 201600430

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

Relevant identified uses

Use of the substance/mixture : Scientific research and development
Technical testing and analysis
For professional use only
Function or use category : Laboratory chemicals

Uses advised against

Restrictions on use : Not for food, drug or home use

1.3. Details of the supplier of the safety data sheet

European Directorate for the Quality of Medicines & Healthcare
EDQM, Council of Europe
7, Allée Kastner, CS30026
F 67081 Strasbourg
France
T +33(0)388412035, F +33(0)388412771
sds@edqm.eu, www.edqm.eu

1.4. Emergency telephone number

Emergency number : +33(0)390215608

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Germ cell mutagenicity, Category 1A H340
Carcinogenicity, Category 2 H351
Reproductive toxicity, Category 1B H360
Specific target organ toxicity – Repeated exposure, Category 1 H372
Hazardous to the aquatic environment – Chronic Hazard, H412
Category 3

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

Adverse physicochemical, human health and environmental effects

Harmful to aquatic life with long lasting effects. Suspected of causing cancer. May cause genetic defects. May damage fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Danger

Gemcitabine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

- Hazard statements (CLP) : H340 - May cause genetic defects.
H351 - Suspected of causing cancer.
H360 - May damage fertility or the unborn child.
H372 - Causes damage to organs (bone marrow, digestive system, nervous system, respiratory system, cardiovascular system) through prolonged or repeated exposure.
H412 - Harmful to aquatic life with long lasting effects.
- Precautionary statements (CLP) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P314 - Get medical advice/attention if you feel unwell.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: Exemption for inner packaging where the contents do not exceed 10ml.

Hazard pictograms (CLP) :



GHS08

2.3. Other hazards

- Other information : Active substance (in pharmaceutical products).
Warning - substance not yet tested completely.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Gemcitabine hydrochloride	CAS-No.: 122111-03-9	≤ 100	Muta. 1A, H340 Carc. 2, H351 Repr. 1B, H360 STOT RE 1, H372 Aquatic Chronic 3, H412

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

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.
- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
- First-aid measures after eye contact : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.
- First-aid measures after ingestion : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

Gemcitabine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

- For containment : Absorb with an inert material and place in an appropriate waste disposal container.
- Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Do not expose pregnant or breastfeeding women.
- Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.
- Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

Gemcitabine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.
Packaging materials	: Keep in original containers.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white, almost white.
Appearance	: Powder.
Molecular mass	: 299.66 g/mol
Odour	: Not available
Odour threshold	: Not available
Melting point	: 287 – 292 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 2 – 3 (1% Aqueous solution)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: 33.3 – 100 g/l

Gemcitabine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Lack of data)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)
Skin corrosion/irritation	: Not classified (Lack of data) pH: 2 – 3 (1% Aqueous solution)
Serious eye damage/irritation	: Not classified (Lack of data) pH: 2 – 3 (1% Aqueous solution)
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: May cause genetic defects.
Carcinogenicity	: Suspected of causing cancer.
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Causes damage to organs (bone marrow, digestive system, nervous system, respiratory system, cardiovascular system) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Lack of data)

11.2. Information on other hazards

No additional information available

Gemcitabine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects.

Gemcitabine hydrochloride (122111-03-9)

EC50 - Crustacea [1]	110 mg/l (48 Hours, Daphnia magna (Water flea)) (EN ISO 6341:1996)
EC50 72h - Algae [1]	45 mg/l (72 Hours, Desmodesmus subspicatus (Green algae)) ((EN ISO8692:1989, DIN 1993)

12.2. Persistence and degradability

Gemcitabine hydrochloride (122111-03-9)

Persistence and degradability	Not rapidly degradable
-------------------------------	------------------------

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
Not regulated for transport		
14.2. UN proper shipping name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated

Gemcitabine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
Not regulated	Not regulated	Not regulated
No supplementary information available		

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (EC 273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.2. Chemical safety assessment

No additional information available

Gemcitabine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Revision date	Added
	Supersedes version of	Added
1.1	CAS-No.	Added
1.1	Synonyms	Removed
1.1	Name	Modified
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
1.2	Main use category	Removed
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.2	Precautionary statements (CLP)	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Hazard pictograms (CLP)	Modified
2.3	Other information	Added
4.1	First-aid measures general	Added
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after inhalation	Modified
4.1	First-aid measures after ingestion	Modified
4.1	First-aid measures after eye contact	Modified
4.2	Symptoms/effects	Removed
4.2	Symptoms/effects after ingestion	Removed
4.2	Symptoms/effects after skin contact	Removed
4.2	Symptoms/effects after inhalation	Removed
4.2	Symptoms/effects after eye contact	Removed
4.3	Other medical advice or treatment	Removed
5.1	Unsuitable extinguishing media	Added
5.1	Suitable extinguishing media	Modified
5.2	Hazardous decomposition products in case of fire	Added
5.2	Fire hazard	Removed
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.1	General measures	Modified

Gemcitabine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Indication of changes		
Section	Changed item	Comments
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Modified
6.4	Reference to other sections (8, 13)	Added
7.1	Additional hazards when processed	Modified
7.1	Precautions for safe handling	Modified
7.1	Hygiene measures	Modified
7.2	Storage conditions	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.3	Specific end uses	Removed
8.2	Respiratory protection	Modified
8.2	Hand protection	Modified
8.2	Eye protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
9	pH	Added
9	Molecular mass	Added
9	Colour	Added
9	Melting point	Added
9	Odour	Removed
10.1	Reactivity	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
11.1	ATE CLP (oral)	Removed
12.1	EC50 - Crustacea [1]	Added
12.1	EC50 72h - Algae [1]	Added
12.1	Ecology - general	Removed
13.1	Regional waste regulation	Removed

Full text of H- and EUH-statements:	
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Carc. 2	Carcinogenicity, Category 2
H340	May cause genetic defects.
H351	Suspected of causing cancer.
H360	May damage fertility or the unborn child.
H372	Causes damage to organs (bone marrow, digestive system, nervous system, respiratory system, cardiovascular system) through prolonged or repeated exposure.

Gemcitabine hydrochloride

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Full text of H- and EUH-statements:

H412	Harmful to aquatic life with long lasting effects.
Muta. 1A	Germ cell mutagenicity, Category 1A
Repr. 1B	Reproductive toxicity, Category 1B
STOT RE 1	Specific target organ toxicity – Repeated exposure, Category 1

Safety Data Sheet (SDS), EU

DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or methods of handling, storage, use or disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. This SDS was prepared and is to be used only for this product. If the product is used as a component in another product, this SDS information may not be applicable. 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.