

According to Regulation (EC) No 1907/2006

According to Regulation (EC) No 2020/878

# Gemcitabine hydrochloride

Version number: 1  
Issued: 2024-02-02



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

### 1.1. Product identifier

**Trade name**

Gemcitabine hydrochloride

**CAS number**

122111-03-9

**EC number**

601-823-3

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

**Relevant identified uses**

Research and development. Laboratory Chemicals. Manufacture of substances.

**Not suitable for use in**

Not suitable for human consumption or veterinary purposes.

### 1.3. Details of the supplier of the safety data sheet

**Supplier**

Molekula Group

Address

Molekula Ltd, Lingfield Way, Darlington,  
DL1 4XX Darlington  
United Kingdom

Telephone

+44 (0) 3302 000 333

Email

info@molekula.com

Web site

www.molekula.com

**Contact person**

Kevin Banks

**Email**

+44 (0) 7769276927

### 1.4. Emergency telephone number

**Poison center/Additional emergency number**

0344 892 0111 - National Poisons Information Service (Newcastle Centre)

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## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

The product is not classified as hazardous according to Regulation (EC) No 1272/2008.

### 2.2. Label elements

The product does not require labelling in accordance with CLP Regulation (EC) No 1272/2008.

### 2.3. Other hazards

No data available

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

Chemical name	CAS No. EC No. REACH No. Index No.	Concentration	Classification	H-phrases M factor acute M factor chronic	Note
Gemcitabine hydrochloride	122111-03-9 601-823-3 - -	100%	Repr. 1B	H360 - -	-

### Molecular weight

299.66

### Substance additional information

For the complete text of H- / EUH-statements mentioned in this section, see section 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

Get medical attention if any discomfort continues. Show this Safety Data Sheet (SDS) to medical personnel.

#### Inhalation

IF INHALED: Remove person to fresh air and keep comfortable for breathing. In case of persistent throat irritation or coughing: Seek medical attention and bring these instructions.

#### Skin contact

IF ON SKIN: Wash with plenty of water. Continue to rinse for at least 15 minutes and seek medical attention. Get medical advice/attention if you feel unwell.

#### Eye contact

Remove contact lenses if present. Rinse eyes with water. Continue to rinse for at least 15 minutes and seek medical attention.

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## Ingestion

IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

## Information for doctors

First aiders/ medical personnel need to protect themselves.

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

The severity of the symptoms described will vary dependant of the concentration and the length of exposure.

## Inhalation

Single exposure may cause the following adverse effects: Upper respiratory irritation. Difficulty in breathing.

## Skin contact

Single exposure may cause the following adverse effects: Severe skin irritation.

## Eye contact

Single exposure may cause the following adverse effects: Severe irritation.

## Ingestion

Single exposure may cause the following adverse effects: Severe abdominal pain. Nausea, vomiting.

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

Treat symptomatically. No special treatment requirement.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### Suitable extinguishing media

In case of fire: Use foam, carbon dioxide, dry powder or water fog to extinguish.

#### Unsuitable extinguishing media

No specific fire fighting procedure given.

### 5.2. Special hazards arising from the substance or mixture

Specific hazards: None.

Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

Carbon dioxide (CO<sub>2</sub>). Carbon monoxide (CO).

Nitrous gases (NO<sub>x</sub>).

Hydrogen Chloride gas

Hydrogen fluoride (HF).

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## 5.3. Advice for firefighters

### Special protective equipment for fire-fighters

Evacuate area. Avoid breathing gas, fume, vapours or spray. Cool containers exposed to heat with water spray and remove container, if no risk is involved.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

Avoid breathing dust/fume/gas/mist/vapours/spray. Provide adequate ventilation. Avoid contact with skin and eyes. For personal protection, see section 8.

### 6.2. Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

### 6.3. Methods and material for containment and cleaning up

Collect spillage with shovel, broom or the like and reuse, if possible. Dispose of large amounts of spillage/waste according to agreement with local authorities.

### 6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Preventive handling precautions

For precautions see section 2.2. Wear protective clothing, gloves, eye and face protection. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapours/spray. Avoid ingestion and inhalation.

#### General hygiene

Observe good chemical hygiene practices. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove contaminated clothing and launder thoroughly before re-use. Wash skin thoroughly after handling.

### 7.2. Conditions for safe storage, including any incompatibilities

Store at ambient temperature. Store in a dry place. Store in a closed container.

### 7.3. Specific end use(s)

No specific usage precautions noted.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No data available

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## 8.2. Exposure controls

### Personal Protective Equipment Symbols



#### Eye / face protection

Wear eye protection.

#### Hand protection

Wear protective gloves.

Always inspect gloves before use. If signs of wear and tear are noticed then the gloves should be replaced.

No specific hygiene procedures noted, but good personal hygiene practices are always advisable, especially when working with chemicals. Wash contaminated skin thoroughly after handling.

#### Other skin protection

Wash skin thoroughly after handling.

#### Respiratory protection

Provide adequate ventilation. If ventilation is insufficient, suitable respiratory protection must be provided.

#### Environmental exposure controls

Avoid discharge into drains.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### Physical state

Solid

#### Colour

White.

#### Odour

Odourless.

#### Melting point / freezing point

287 - 292 °C

#### Boiling point or initial boiling point and boiling range

No data available

#### Flammability

No data available

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## Lower and upper explosion limit

No data available

## Flash point

No data available

## Auto-ignition temperature

No data available

## Decomposition temperature

No data available

## pH

No data available

## Kinematic viscosity

No data available

## Solubility

No data available

## Partition coefficient n-octanol/water

No data available

## Vapour pressure

No data available

## Density and/or relative density

No data available

## Relative vapour density

No data available

## Particle characteristics

No data available

## 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

There are no known reactivity hazards associated with this product.

### 10.2. Chemical stability

Stable under the prescribed storage conditions.

### 10.3. Possibility of hazardous reactions

No data available

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## 10.4. Conditions to avoid

strong heating

## 10.5. Incompatible materials

Strong oxidising agents.

## 10.6. Hazardous decomposition products

See section 5.

## SECTION 11: Toxicological information

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

#### Acute toxicity

Product / Substance name CAS / EC no.	Dose descriptor	Value / Dose	Exposure route	Test animals
Gemcitabine hydrochloride 122111-03-9 / 601-823-3	TDL <sub>0</sub>	300 mg/kg	Parenteral	Human
Gemcitabine hydrochloride 122111-03-9 / 601-823-3	LD <sub>50</sub>	236 mg/kg	Intravenous.	Rat
Gemcitabine hydrochloride 122111-03-9 / 601-823-3	LD <sub>50</sub>	500 mg/kg	Intravenous.	Mouse

#### Reproductive toxicity

Product / Substance name CAS / EC no.	Result
Gemcitabine hydrochloride 122111-03-9 / 601-823-3	Possible reproductive impact.

#### Aspiration hazard

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

### 11.2. Information on other hazards

No data available

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## SECTION 12: Ecological information

### 12.1. Toxicity

No data available

### 12.2. Persistence and degradability

No data available

### 12.3. Bioaccumulative potential

No data available

### 12.4. Mobility in soil

No data available

### 12.5. Results of PBT and vPvB assessment

No data available

### 12.6. Endocrine disrupting properties

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

### 12.7. Other adverse effects

No data available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Disposal considerations

Dispose of contents/container in accordance with local/regional/national/international regulations.

## SECTION 14: Transport information

### 14.1. UN number

Not applicable

### 14.2. UN proper shipping name

Not applicable

### 14.3. Transport hazard class(es)

Not applicable

### 14.4. Packing group

Not applicable

### 14.5. Environmental hazards

Not applicable

### 14.6. Special precautions for user

Not applicable



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## 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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

This material safety data sheet complies with the requirements of Regulation (EU) 2020/878.

#### National regulations

No data available

### 15.2. Chemical safety assessment

No data available

## SECTION 16: Other information

#### Phrase meaning

Repr. 1B - Reproductive toxicity, hazard category 1B

H360 May damage fertility or the unborn child.