

Yangzhou Sunchem Co.,Ltd.

Material Safety Data Sheet

Gemcitabine

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product name : Gemcitabine hydrochloride

CAS-No. : 122111-03-9

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

Identified uses : Laboratory chemicals, Manufacture of substances

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.2 Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

Reproductive toxicity (Category 1B)

Classification according to EU Directives 67/548/EEC or 1999/45/EC

Possible risk of impaired fertility. Possible risk of harm

to the unborn child.

2.2 Label elements

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

Pictogram

Signal word Danger

Hazard statement(s)

H360 May damage fertility or the unborn child.

Precautionary statement(s)

P201 Obtain special instructions before use.

P308 + P313 IF exposed or concerned: Get medical advice/
attention.

Supplemental Hazard none

Statements

Restricted to professional users.

According to European Directive 67/548/EEC as amended.

Hazard symbol(s)

R-phrase(s)

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.

S-phrase(s)

S36/37 Wear suitable protective clothing and gloves.

S53 Avoid exposure – obtain special instructions before use.

2.3 Other hazards – none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Formula: $C_9H_{11}F_2N_3O_4 \cdot HCl$

Molecular Weight: 299,66 g/mol

Component	Concentration
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Gemcitabine hydrochloride	
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CAS-No. 122111-03-9	–
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4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person.

Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

Fever, Nausea, Vomiting, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

4.3 Indication of any immediate medical attention and special treatment needed

no data available

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, nitrogen oxides (NO_x), Hydrogen chloride gas, Hydrogen fluoride

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

no data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid formation of dust and aerosols. Avoid exposure – obtain special instructions before use.

Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Light sensitive.

7.3 Specific end uses

no data available

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at

the end of workday.

Personal protective equipment

Eye/face protection

Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

impervious clothing, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the

specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance Form: solid

b) Odour no data available

c) Odour Threshold no data available

d) pH no data available

e) Melting point/freezing point no data available

f) Initial boiling point and boiling range no data available

g) Flash point no data available

h) Evaporation rate no data available

- i) Flammability (solid, gas) no data available
- j) Upper/lower flammability or explosive limits no data available
- k) Vapour pressure no data available
- l) Vapour density no data available
- m) Relative density no data available
- n) Water solubility no data available
- o) Partition coefficient: noctanol/water no data available
- p) Autoignition temperature no data available
- q) Decomposition temperature no data available
- r) Viscosity no data available
- s) Explosive properties no data available
- t) Oxidizing properties no data available

9.20ther safety information

no data available

10. STABILITY AND REACTIVITY

10.1Reactivity

no data available

10.2Chemical stability

no data available

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Other decomposition products - no data available

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

no data available

TDLo Parenteral - Human - female - 300 mg/kg

Remarks: Lungs, Thorax, or Respiration:Dyspnea. Lungs, Thorax, or Respiration:Fibrosis, focal(pneumoconiosis).

Lungs, Thorax, or Respiration:Other changes.

LD50 Intravenous - rat - 236 mg/kg

LD50 Intravenous - mouse - 500 mg/kg

Skin corrosion/irritation

no data available

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

no data available

Suspected human reproductive toxicant

Presumed human reproductive toxicant

Specific target organ toxicity – single exposure

no data available

Specific target organ toxicity – repeated exposure

no data available

Aspiration hazard

no data available

Potential health effects

Inhalation May be harmful if inhaled. May cause respiratory

tract irritation.

Ingestion May be harmful if swallowed.

Skin May be harmful if absorbed through skin. May cause skin irritation.

Eyes May cause eye irritation.

Signs and Symptoms of Exposure

Fever, Nausea, Vomiting, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Additional Information

Repeated dose toxicity - Mammal

Blood:Thrombocytopenia.

Repeated dose toxicity - Mammal

Blood:Thrombocytopenia.

Repeated dose toxicity - Mammal

Blood:Thrombocytopenia.

Repeated dose toxicity - Mammal

Blood:Thrombocytopenia.

Repeated dose toxicity - Mammal

Repeated dose toxicity - Mammal

Repeated dose toxicity - mouse

Repeated dose toxicity - mouse

RTECS: Not available

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 Other adverse effects

no data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent

and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for user

no data available

15. REGULATORY INFORMATION

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

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

no data available

15.2 Chemical Safety Assessment

no data available

16. OTHER INFORMATION

WARRANTY:

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. sunchem shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.

