

Version: 1.0

Creation Date: Aug 20, 2018 Revision Date: Aug 20, 2018

#### 1.Identification

#### 1.1 GHS Product identifier

**Product name** Gemcitabine

### 1.2 Other means of identification

**Product number** AO683

3-DEOXY-2,2-DIFLUORO-D-RIBOFURANOSE-3,5-DIBENZOATE Other names

#### 1.3 Recommended use of the chemical and restrictions on use

**Identified uses** For industry use only. Uses advised against no data available

## 1.4 Supplier's details

**Company** Acros PharmaTech Limited

HongKong: Unit 3A-8,12/F,Kaiser Centre,No.18 Centre Street,Sai Ying Pun,HongKong **Address** 

Mainland: Suite 920, Changwu Road 888, Changzhou, Jiangsu, China

**Telephone** 86(519)85265509

#### 2. Hazard identification

#### 2.1 Classification of the substance or mixture

Acute toxicity - Oral, Category 4

Acute toxicity - Dermal, Category 4

Skin irritation, Category 2

Eye irritation, Category 2

Germ cell mutagenicity, Category 1B

Carcinogenicity, Category 2

Reproductive toxicity, Category 1B

Specific target organ toxicity - repeated exposure, Category 1

Hazardous to the aquatic environment, long-term (Chronic) - Category Chronic 2

# 2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word

Danger

H302 Harmful if swallowed

Hazard statement(s)

H312 Harmful in contact with skin



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H315 Causes skin irritation

H319 Causes serious eye 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

H411 Toxic to aquatic life with long lasting effects

**Precautionary** statement(s)

P264 Wash ... thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Prevention 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.

P273 Avoid release to the environment.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor/...if you feel unwell.

P330 Rinse mouth.

P302+P352 IF ON SKIN: Wash with plenty of water/...

P312 Call a POISON CENTER/doctor/...if you feel unwell.

P321 Specific treatment (see ... on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

Response

P332+P313 If skin irritation occurs: Get medical advice/attention.

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.

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

P314 Get medical advice/attention if you feel unwell.

P391 Collect spillage.

Storage P405 Store locked up.

Disposal P501 Dispose of contents/container to ...

### 2.3 Other hazards which do not result in classification

none

## 3. Composition/information on ingredients

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#### 3.1 Substances

#### Chemical name Common names and synonyms CAS number EC number Concentration

Gemcitabine Gemcitabine 95058-81-4 none ≥98%+

#### 4. First-aid measures

## 4.1 Description of necessary 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

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

#### If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

## 4.2 Most important symptoms/effects, acute and delayed

no data available

#### 4.3 Indication of immediate medical attention and special treatment needed, if necessary

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 Specific hazards arising from the chemical

no data available

### 5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

#### 6.Accidental release measures

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

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

#### 6.2 Environmental precautions



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Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

# 6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal. Sweep up and shovel. Keep in suitable, closed containers for disposal.

#### 7. Handling and storage

#### 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Avoid exposure - obtain special instructions before use. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

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

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

## 8.Exposure controls/personal protection

#### 8.1 Control parameters

## Occupational Exposure limit values

no data available

#### **Biological limit values**

no data available

#### 8.2 Appropriate engineering controls

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

## 8.3 Individual protection measures, such as personal protective equipment (PPE)

#### **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

Wear impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. 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.

# **Respiratory protection**

Wear dust mask when handling large quantities.

#### Thermal hazards

no data available

#### 9. Physical and chemical properties

Physical state

no data available



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Colour no data available Odour no data available 168.64°C Melting point/ freezing point Boiling point or initial boiling point and boiling range no data available **Flammability** no data available Lower and upper explosion limit / flammability limit no data available Flash point no data available **Auto-ignition temperature** no data available **Decomposition temperature** no data available рΗ no data available no data available

Kinematic viscosity no data available Solubility Partition coefficient n-octanol/water (log value) no data available no data available Vapour pressure Density and/or relative density no data available no data available Relative vapour density **Particle characteristics** no data available

## 10.Stability and reactivity

## 10.1 Reactivity

no data available

## 10.2 Chemical stability

Stable under recommended storage conditions.

#### 10.3 Possibility of hazardous reactions

no data available

# 10.4 Conditions to avoid

no data available

# 10.5 Incompatible materials

no data available

### 10.6 Hazardous decomposition products

no data available

## 11.Toxicological information

## **Acute toxicity**

- Oral: no data available
- Inhalation: no data available
- Dermal: no data available

## Skin corrosion/irritation

no data available

## Serious eye damage/irritation



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no data available

#### Respiratory or skin sensitization

no data available

### Germ cell mutagenicity

no data available

## Carcinogenicity

no data available

#### Reproductive toxicity

no data available

## STOT-single exposure

no data available

#### STOT-repeated exposure

no data available

#### **Aspiration hazard**

no data available

# 12. Ecological information

## **12.1 Toxicity**

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: 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 Other adverse effects

no data available

# 13.Disposal considerations

## 13.1 Disposal methods

**Product** 



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The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

### Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

## 14.Transport information

### 14.1 UN Number

ADR/RID: no data available IMDG: no data available IATA: no data available

## 14.2 UN Proper Shipping Name

ADR/RID: no data available IMDG: no data available IATA: no data available

# 14.3 Transport hazard class(es)

ADR/RID: no data available IMDG: no data available IATA: no data available

## 14.4 Packing group, if applicable

ADR/RID: no data available IMDG: no data available IATA: no data available

## 14.5 Environmental hazards

ADR/RID: yes IMDG: yes IATA: yes

## 14.6 Special precautions for user

no data available

# 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

## 15.Regulatory information

#### 15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
Gemcitabine	Gemcitabine	95058-81-4	none
<b>European Inventory of Existing Commercial Chemical Substances (EINECS)</b>			Not Listed.
EC Inventory			Not Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Not Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Invent	tory of Chemicals (NZIoC)		Not Listed.
<b>Philippines Invento</b>	ry of Chemicals and Chemical Substance	es (PICCS)	Not Listed.
<b>Vietnam National C</b>	hemical Inventory		Not Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Not Listed.

## 16.Other information



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#### Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

#### References

- IPCS The International Chemical Safety Cards (ICSC), website: http://www.ilo.org/dyn/icsc/showcard.home
- HSDB Hazardous Substances Data Bank, website: https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm
- IARC International Agency for Research on Cancer, website: http://www.iarc.fr/
- eChemPortal The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request\_locale=en
- CAMEO Chemicals, website: http://cameochemicals.noaa.gov/search/simple
- ChemIDplus, website: http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp
- ERG Emergency Response Guidebook by U.S. Department of Transportation, website: http://www.phmsa.dot.gov/hazmat/library/erg
- Germany GESTIS-database on hazard substance, website: http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp
- ECHA European Chemicals Agency, website: https://echa.europa.eu/

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