

Creation Date 11-Mar-2016

Revision Date 11-Mar-2016

Revision Number 1

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identification

**Product Description:** Gemcitabine hydrochloride  
**Cat No. :** 461060000, 461060010, 461060050  
**Synonyms** 2',2'-Difluorodeoxycytidine hydrochloride  
**CAS-No** 122111-03-9  
**Molecular Formula** C9 H11 F2 N3 O4 . H Cl

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

**Recommended Use** Laboratory chemicals.  
**Uses advised against** No Information available

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

**Company** Acros Organics BVBA  
Janssen Pharmaceuticaaan 3a  
2440 Geel, Belgium  
**E-mail address** begel.sdsdesk@thermofisher.com

### 1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11  
Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99  
**CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

#### CLP Classification - Regulation (EC) No 1272/2008

##### Physical hazards

Based on available data, the classification criteria are not met

##### Health hazards

Acute dermal toxicity	Category 4
Skin Corrosion/Irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 2
Germ Cell Mutagenicity	Category 1B
Reproductive Toxicity	Category 1B

##### Environmental hazards

Based on available data, the classification criteria are not met

### 2.2. Label elements

# SAFETY DATA SHEET

Gemcitabine hydrochloride

Revision Date 11-Mar-2016



**Signal Word**

**Danger**

## Hazard Statements

- H312 - Harmful in contact with skin
- H315 - Causes skin irritation
- H319 - Causes serious eye irritation
- H340 - May cause genetic defects
- H360 - May damage fertility or the unborn child

## Precautionary Statements

- P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
- P312 - Call a POISON CENTER or doctor/ physician if you feel unwell
- P337 + P313 - If eye irritation persists: Get medical advice/ attention
- P201 - Obtain special instructions before use
- P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection

## Additional EU labelling

Restricted to professional users

## 2.3. Other hazards

No information available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Component	CAS-No	EC-No.	Weight %	CLP Classification - Regulation (EC) No 1272/2008
Gemcitabine hydrochloride	122111-03-9		>95	Acute Tox. 4 (H312) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Muta. 1B (H340) Repr. 1B (H360)

Full text of Hazard Statements: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

#### General Advice

If symptoms persist, call a physician.

#### Eye Contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

#### Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

#### Ingestion

Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.

# SAFETY DATA SHEET

Gemcitabine hydrochloride

Revision Date 11-Mar-2016

<b>Inhalation</b>	Move to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
<b>Protection of First-aiders</b>	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

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

None reasonably foreseeable.

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

**Notes to Physician** Treat symptomatically.

## **SECTION 5: FIREFIGHTING MEASURES**

#### **5.1. Extinguishing media**

##### **Suitable Extinguishing Media**

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

##### **Extinguishing media which must not be used for safety reasons**

No information available.

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

Thermal decomposition can lead to release of irritating gases and vapors.

##### **Hazardous Combustion Products**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Hydrogen fluoride, Nitrogen oxides (NO<sub>x</sub>), Hydrogen chloride.

#### **5.3. Advice for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

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

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation.

#### **6.2. Environmental precautions**

Should not be released into the environment.

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

Sweep up or vacuum up spillage and collect in suitable container for disposal. Keep in suitable, closed containers for disposal.

#### **6.4. Reference to other sections**

Refer to protective measures listed in Sections 8 and 13.

## **SECTION 7: HANDLING AND STORAGE**

#### **7.1. Precautions for safe handling**

Wear personal protective equipment. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation. Use only under a chemical fume hood.

# SAFETY DATA SHEET

Gemcitabine hydrochloride

Revision Date 11-Mar-2016

## Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing before re-use. Wash hands before breaks and at the end of workday.

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

Keep container tightly closed in a dry and well-ventilated place. Protect from light. To maintain product quality: Keep refrigerated.

## 7.3. Specific end use(s)

Use in laboratories

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

#### Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

#### Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

**Derived No Effect Level (DNEL)** No information available

<u>Route of exposure</u>	<b>Acute effects (local)</b>	<b>Acute effects (systemic)</b>	<b>Chronic effects (local)</b>	<b>Chronic effects (systemic)</b>
Oral Dermal Inhalation				

**Predicted No Effect Concentration (PNEC)** No information available.

### 8.2. Exposure controls

#### Engineering Measures

Ensure that eyewash stations and safety showers are close to the workstation location.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

#### Personal protective equipment

**Eye Protection**  
**Hand Protection**

Goggles (European standard - EN 166)  
Protective gloves

# SAFETY DATA SHEET

Gemcitabine hydrochloride

Revision Date 11-Mar-2016

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Nitrile rubber	See manufacturers recommendations	-	EN 374	(minimum requirement)
Neoprene				
Natural rubber				
PVC				

**Skin and body protection**      Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatibility, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

**Respiratory Protection**

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly

**Large scale/emergency use**

Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced

**Recommended Filter type:** Particulates filter conforming to EN 143

**Small scale/Laboratory use**

Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

**Recommended half mask:-** Particle filtering: EN149:2001

When RPE is used a face piece Fit Test should be conducted

**Environmental exposure controls**      No information available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

<b>Appearance</b>	White	
<b>Physical State</b>	Solid	
<b>Odor</b>	No information available	
<b>Odor Threshold</b>	No data available	
<b>pH</b>	No information available	
<b>Melting Point/Range</b>	No data available	
<b>Softening Point</b>	No data available	
<b>Boiling Point/Range</b>	No information available	
<b>Flash Point</b>	No information available	<b>Method -</b> No information available
<b>Evaporation Rate</b>	Not applicable	Solid
<b>Flammability (solid,gas)</b>	No information available	
<b>Explosion Limits</b>	No data available	
<b>Vapor Pressure</b>	No data available	
<b>Vapor Density</b>	Not applicable	Solid
<b>Specific Gravity / Density</b>	No data available	
<b>Bulk Density</b>	No data available	
<b>Water Solubility</b>	soluble	
<b>Solubility in other solvents</b>	No information available	
<b>Partition Coefficient (n-octanol/water)</b>		
<b>Autoignition Temperature</b>	Not applicable	
<b>Decomposition Temperature</b>	No data available	
<b>Viscosity</b>	Not applicable	Solid
<b>Explosive Properties</b>	No information available	
<b>Oxidizing Properties</b>	No information available	

**9.2. Other information**

# SAFETY DATA SHEET

Gemcitabine hydrochloride

Revision Date 11-Mar-2016

Molecular Formula C9 H11 F2 N3 O4 . H Cl  
Molecular Weight 299.66

## SECTION 10: STABILITY AND REACTIVITY

**10.1. Reactivity** None known, based on information available

**10.2. Chemical stability** Light sensitive

**10.3. Possibility of hazardous reactions**

**Hazardous Polymerization** Hazardous polymerization does not occur.  
**Hazardous Reactions** None under normal processing.

**10.4. Conditions to avoid** Exposure to light.

**10.5. Incompatible materials** Strong oxidizing agents.

**10.6. Hazardous decomposition products** Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>). Hydrogen fluoride. Nitrogen oxides (NO<sub>x</sub>). Hydrogen chloride.

## SECTION 11: TOXICOLOGICAL INFORMATION

**11.1. Information on toxicological effects**

**Product Information**

**(a) acute toxicity;**

**Oral** No data available  
**Dermal** Category 4  
**Inhalation** No data available

**(b) skin corrosion/irritation;** Category 2

**(c) serious eye damage/irritation;** Category 2

**(d) respiratory or skin sensitization;**

**Respiratory** No data available  
**Skin** No data available

**(e) germ cell mutagenicity;** Category 1B

**(f) carcinogenicity;** No data available

There are no known carcinogenic chemicals in this product

**(g) reproductive toxicity;** Category 1B  
**Reproductive Effects** May impair fertility. May cause harm to the unborn child.

**(h) STOT-single exposure;** No data available

**(i) STOT-repeated exposure;** No data available

**Target Organs** None known.

# SAFETY DATA SHEET

Gemcitabine hydrochloride

Revision Date 11-Mar-2016

(j) aspiration hazard; Not applicable  
Solid

Symptoms / effects, both acute and delayed No information available

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### Ecotoxicity effects

Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

### 12.2. Persistence and degradability

#### Persistence

Soluble in water, Persistence is unlikely, based on information available.

### 12.3. Bioaccumulative potential

Bioaccumulation is unlikely

### 12.4. Mobility in soil

The product is water soluble, and may spread in water systems Will likely be mobile in the environment due to its water solubility. Highly mobile in soils

### 12.5. Results of PBT and vPvB assessment

No data available for assessment.

### 12.6. Other adverse effects

**Endocrine Disruptor Information**  
**Persistent Organic Pollutant**  
**Ozone Depletion Potential**

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

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

#### **Waste from Residues / Unused Products**

Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

#### **Contaminated Packaging**

Dispose of this container to hazardous or special waste collection point.

#### **European Waste Catalogue (EWC)**

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.

#### **Other Information**

Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains.

## SECTION 14: TRANSPORT INFORMATION

### IMDG/IMO

Not regulated

### 14.1. UN number

### 14.2. UN proper shipping name

### 14.3. Transport hazard class(es)

### 14.4. Packing group

### ADR

Not regulated

### 14.1. UN number

### 14.2. UN proper shipping name

### 14.3. Transport hazard class(es)

### 14.4. Packing group

### IATA

Not regulated

# SAFETY DATA SHEET

Gemcitabine hydrochloride

Revision Date 11-Mar-2016

**14.1. UN number**

**14.2. UN proper shipping name**

**14.3. Transport hazard class(es)**

**14.4. Packing group**

**14.5. Environmental hazards** No hazards identified

**14.6. Special precautions for user** No special precautions required

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable, packaged goods

## SECTION 15: REGULATORY INFORMATION

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

**International Inventories** Complete Regulatory Information contained in following SDS's X = listed The product is classified and labeled according to EC directives or corresponding national laws The product is classified and labeled in accordance with Directive 1999/45/EC

#### National Regulations

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment.  
Take note of Dir 94/33/EC on the protection of young people at work  
Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work  
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

### 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

## SECTION 16: OTHER INFORMATION

### Full Text of H-/EUH-Statements Referred to Under Section 3

H312 - Harmful in contact with skin  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H340 - May cause genetic defects  
H360 - May damage fertility or the unborn child

#### Legend

**CAS** - Chemical Abstracts Service

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

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**IECSC** - Chinese Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

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

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

**ENCS** - Japanese Existing and New Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**WEL** - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level

**RPE** - Respiratory Protective Equipment

**LC50** - Lethal Concentration 50%

**NOEC** - No Observed Effect Concentration

**PBT** - Persistent, Bioaccumulative, Toxic

**TWA** - Time Weighted Average

**IARC** - International Agency for Research on Cancer

**PNEC** - Predicted No Effect Concentration

**LD50** - Lethal Dose 50%

**EC50** - Effective Concentration 50%

**POW** - Partition coefficient Octanol:Water

**vPvB** - very Persistent, very Bioaccumulative



# SAFETY DATA SHEET

Gemcitabine hydrochloride

Revision Date 11-Mar-2016

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road

**IMO/MDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association

**MARPOL** - International Convention for the Prevention of Pollution from Ships

**ATE** - Acute Toxicity Estimate

**VOC** - Volatile Organic Compounds

## Key literature references and sources for data

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

## Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

**Creation Date** 11-Mar-2016

**Revision Date** 11-Mar-2016

**Revision Summary** Not applicable.

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

## Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of Safety Data Sheet**