

| | | |
|---|-------------------------------------|------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 1 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Gemcitabine for Injection, USP

1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutual, use only as directed. Refer to product insert for product information and usage instructions. Medical Treatment: Antineoplastic.

Use of the Substance/Mixture: For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Meitheal Pharmaceuticals, Inc.
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631
224-443-4617

www.meithealpharma.com

1.4. Emergency Telephone Number

Emergency Number : 844-824-8426

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

| | |
|---------------------|------|
| Acute Tox. 4 (Oral) | H302 |
| Skin Irrit. 2 | H315 |
| Eye Irrit. 2 | H319 |
| Muta. 1B | H340 |
| Carc. 2 | H351 |
| Repr. 1B | H360 |
| STOT RE 1 | H372 |
| Comb. Dust | |

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



Signal Word (GHS-US) :

Danger

Hazard Statements (GHS-US) :

May form combustible dust concentrations in air.
H302 - Harmful if swallowed.
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H340 - May cause genetic defects.
H351 - Suspected of causing cancer.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

| | | |
|---|-------------------------------------|------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 2 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

Precautionary Statements (GHS-US) :

H360 - May damage fertility or the unborn child.
H372 - Causes damage to organs through prolonged or repeated exposure.
P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P260 - Do not breathe dust.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P280 - Wear protective gloves, protective clothing, and eye protection.
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.
P302+P352 - If on skin: Wash with plenty of water.
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - If exposed or concerned: Get medical advice/attention.
P314 - Get medical advice/attention if you feel unwell.
P321 - Specific treatment (see section 4 on this SDS).
P330 - Rinse mouth.
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P405 - Store locked up.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

| Name | Product Identifier | % | GHS-US classification |
|---------------------------|-----------------------|------|---|
| Gemcitabine hydrochloride | (CAS-No.) 122111-03-9 | 50.8 | Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Muta. 1B, H340 Carc. 2, H351 Repr. 1B, H360 STOT RE 1, H372 Aquatic Chronic 2, H411 |
| D-Mannitol | (CAS-No.) 69-65-8 | 44.6 | Comb. Dust |
| Sodium acetate trihydrate | (CAS-No.) 6131-90-4 | 4.6 | Not classified |

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

| | | |
|---|-------------------------------------|------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 3 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

| | | | |
|-------------------|---------------------|----------|---|
| Hydrochloric acid | (CAS-No.) 7647-01-0 | 0.000001 | Press. Gas (Comp.), H280 Acute Tox. 3 (Inhalation:gas), H331 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 |
| Sodium hydroxide | (CAS-No.) 1310-73-2 | 0.000001 | Met. Corr. 1, H290 Acute Tox. 3 (Oral), H301 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402 |

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: Using proper respiratory protection, move the exposed person to fresh air at once. Encourage exposed person to cough, spit out, and blow nose to remove dust. Immediately call a poison center, physician, or emergency medical service.

First-aid Measures After Skin Contact: Remove contaminated clothing. Immediately drench affected area with water for at least 15 minutes. If exposed or concerned: Get medical advice/attention.

First-aid Measures After Eye Contact: Immediately rinse with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Causes damage to organs through prolonged or repeated exposure. Causes skin irritation. Causes serious eye irritation. May cause genetic defects. Suspected of causing cancer. May damage fertility. May damage the unborn child. Harmful if swallowed.

Symptoms/Injuries After Inhalation: Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: Causes damage to organs through prolonged or repeated exposure. May cause genetic defects. Suspected of causing cancer. May damage fertility or the unborn child.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

| | | |
|---|-------------------------------------|------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 4 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Combustible Dust.

Explosion Hazard: Dust explosion hazard in air.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂).

Other Information: Risk of dust explosion.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe dust. Do not get in eyes, on skin, or on clothing. Avoid generating dust. Remove ignition sources. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit.

Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams. Avoid generation of dust during clean-up of spills.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Contact competent authorities after a spill.

Use explosion proof vacuum during cleanup, with appropriate filter. Do not mix with other materials. Vacuum clean-up is preferred. If sweeping is required use a dust suppressant. Use only non-sparking tools.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

| | | |
|---|-------------------------------------|------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 5 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not breathe dust. Avoid contact with eyes, skin and clothing. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Handle empty containers with care because they may still present a hazard. Avoid creating or spreading dust. Keep away from heat, sparks, open flames, and hot surfaces. No smoking.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations. Avoid creating or spreading dust. Use explosion-proof electrical, ventilating, lighting equipment. Proper grounding procedures to avoid static electricity should be followed.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store/locked up/in a secure area.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions.

Medical Treatment: Antineoplastic. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

| Hydrochloric acid (7647-01-0) | | |
|-------------------------------|--|--|
| USA ACGIH | ACGIH Ceiling (ppm) | 2 ppm |
| USA ACGIH | ACGIH chemical category | Not Classifiable as a Human Carcinogen |
| USA NIOSH | NIOSH REL (ceiling) (mg/m ³) | 7 mg/m ³ |
| USA NIOSH | NIOSH REL (ceiling) (ppm) | 5 ppm |
| USA IDLH | US IDLH (ppm) | 50 ppm |
| USA OSHA | OSHA PEL (Ceiling) (mg/m ³) | 7 mg/m ³ |
| USA OSHA | OSHA PEL (Ceiling) (ppm) | 5 ppm |
| Sodium hydroxide (1310-73-2) | | |
| USA ACGIH | ACGIH Ceiling (mg/m ³) | 2 mg/m ³ |
| USA NIOSH | NIOSH REL (ceiling) (mg/m ³) | 2 mg/m ³ |
| USA IDLH | US IDLH (mg/m ³) | 10 mg/m ³ |
| USA OSHA | OSHA PEL (TWA) (mg/m ³) | 2 mg/m ³ |

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.

| | | |
|---|-------------------------------------|------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 6 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed. Proper grounding procedures to avoid static electricity should be followed. Use explosion-proof equipment. Use local exhaust or general dilution ventilation or other suppression methods to maintain dust levels below exposure limits. Power equipment should be equipped with proper dust collection devices. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

| | |
|---------------------------|---|
| Physical State | : Solid |
| Appearance | : White to off-white, lyophilized powder |
| Odor | : No data available |
| Odor Threshold | : No data available |
| pH | : 2.7 - 3.3 upon reconstitution with NaCl |
| Evaporation Rate | : No data available |
| Melting Point | : No data available |
| Freezing Point | : No data available |
| Boiling Point | : No data available |
| Flash Point | : No data available |
| Auto-ignition Temperature | : No data available |
| Decomposition Temperature | : No data available |
| Flammability (solid, gas) | : No data available |



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

| | | |
|---|-------------------------------------|------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 7 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

| | |
|---|---------------------|
| Vapor Pressure | : No data available |
| Relative Vapor Density at 20°C | : No data available |
| Relative Density | : No data available |
| Solubility | : Soluble. |
| Partition Coefficient: N-Octanol/Water | : No data available |
| Viscosity | : No data available |

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. **Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. **Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials. Sparks, heat, open flame and other sources of ignition. Dust accumulation (to minimize explosion hazard).
- 10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** Does not decompose.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Oral: Harmful if swallowed.

| | |
|--|--------------------------------|
| Gemcitabine for Injection, USP | |
| ATE (Oral) | 984.25 mg/kg body weight |
| Gemcitabine hydrochloride (122111-03-9) | |
| ATE (Oral) | 500.00 mg/kg body weight |
| ATE (Dermal) | 1,100.00 mg/kg body weight |
| D-Mannitol (69-65-8) | |
| LD50 Oral Rat | 13500 mg/kg |
| Hydrochloric acid (7647-01-0) | |
| LD50 Oral Rat | 238 (238 - 277) mg/kg |
| LD50 Dermal Rabbit | > 5010 mg/kg |
| LC50 Inhalation Rat | 1.68 mg/l (Exposure time: 1 h) |
| LC50 Inhalation Rat | 1411 ppm |
| LC50 Inhalation Rat | 0.42 mg/l/4h |
| ATE (Gases) | 700.00 ppmV/4h |
| ATE (Vapors) | 1.68 mg/l/4h |
| Sodium hydroxide (1310-73-2) | |
| LD50 Oral Rat | 140 - 340 mg/kg |
| ATE (Oral) | 140.00 mg/kg body weight |

Skin Corrosion/Irritation: Causes skin irritation.

pH: 2.7 - 3.3 upon reconstitution with NaCl

Serious Eye Damage/Irritation: Causes serious eye irritation.

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

| | | |
|---|-------------------------------------|------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 8 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

pH: 2.7 - 3.3 upon reconstitution with NaCl

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: May cause genetic defects.

Carcinogenicity: Suspected of causing cancer.

| | |
|-------------------------------|---|
| Hydrochloric acid (7647-01-0) | |
| IARC group | 3 |

Reproductive Toxicity: May damage fertility or the unborn child.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Causes damage to organs through prolonged or repeated exposure.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Dust may be harmful or cause irritation.

Symptoms/Injuries After Skin Contact: Redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: Causes damage to organs through prolonged or repeated exposure. May cause genetic defects. Suspected of causing cancer. May damage fertility or the unborn child.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

| | |
|-------------------------------|---|
| Hydrochloric acid (7647-01-0) | |
| EC50 Daphnia 1 | 0.492 mg/l |
| Sodium hydroxide (1310-73-2) | |
| LC50 Fish 1 | 45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static]) |
| EC50 Daphnia 1 | 40 mg/l |

12.2. Persistence and Degradability

| | |
|--------------------------------|------------------|
| Gemcitabine for Injection, USP | |
| Persistence and Degradability | Not established. |

12.3. Bioaccumulative Potential

| | |
|--------------------------------|------------------|
| Gemcitabine for Injection, USP | |
| Bioaccumulative Potential | Not established. |

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment.

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

| | | |
|---|-------------------------------------|------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 9 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

- 14.1. **In Accordance with DOT** Not regulated for transport
- 14.2. **In Accordance with IMDG** Not regulated for transport
- 14.3. **In Accordance with IATA** Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

| | |
|---|--|
| Gemcitabine for Injection, USP | |
| SARA Section 311/312 Hazard Classes | Health hazard - Specific target organ toxicity (single or repeated exposure) Health hazard - Skin corrosion or Irritation Health hazard - Serious eye damage or eye irritation Health hazard - Germ cell mutagenicity Health hazard - Carcinogenicity Health hazard - Reproductive toxicity Health hazard - Acute toxicity (any route of exposure) Physical hazard - Combustible dust |
| D-Mannitol (69-65-8) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |
| Hydrochloric acid (7647-01-0) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |
| Listed on the United States SARA Section 302 | |
| Subject to reporting requirements of United States SARA Section 313 | |
| CERCLA RQ | 5000 lb |
| SARA Section 302 Threshold Planning Quantity (TPQ) | 500 lb (gas only) |
| SARA Section 313 - Emission Reporting | 1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size) |
| Sodium hydroxide (1310-73-2) | |
| Listed on the United States TSCA (Toxic Substances Control Act) inventory | |
| CERCLA RQ | 1000 lb |

15.2. US State Regulations

| |
|---|
| Hydrochloric acid (7647-01-0) |
| U.S. - Massachusetts - Right To Know List |
| U.S. - New Jersey - Right to Know Hazardous Substance List |
| U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List |
| U.S. - Pennsylvania - RTK (Right to Know) List |
| Sodium hydroxide (1310-73-2) |
| U.S. - Massachusetts - Right To Know List |
| U.S. - New Jersey - Right to Know Hazardous Substance List |

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

| | | |
|---|-------------------------------------|-------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 10 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

| |
|---|
| U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List |
| U.S. - Pennsylvania - RTK (Right to Know) List |

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 10/03/2018
 Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

| | |
|-------------------------------|--|
| Acute Tox. 3 (Inhalation:gas) | Acute toxicity (inhalation:gas) Category 3 |
| Acute Tox. 3 (Oral) | Acute toxicity (oral) Category 3 |
| Acute Tox. 4 (Dermal) | Acute toxicity (dermal) Category 4 |
| Acute Tox. 4 (Oral) | Acute toxicity (oral) Category 4 |
| Aquatic Acute 1 | Hazardous to the aquatic environment - Acute Hazard Category 1 |
| Aquatic Acute 3 | Hazardous to the aquatic environment - Acute Hazard Category 3 |
| Aquatic Chronic 2 | Hazardous to the aquatic environment - Chronic Hazard Category 2 |
| Carc. 2 | Carcinogenicity Category 2 |
| Comb. Dust | Combustible Dust |
| Eye Dam. 1 | Serious eye damage/eye irritation Category 1 |
| Eye Irrit. 2 | Serious eye damage/eye irritation Category 2 |
| Eye Irrit. 2A | Serious eye damage/eye irritation Category 2A |
| Met. Corr. 1 | Corrosive to metals Category 1 |
| Muta. 1B | Germ cell mutagenicity Category 1B |
| Press. Gas (Comp.) | Gases under pressure Compressed gas |
| Repr. 1B | Reproductive toxicity Category 1B |
| Skin Corr. 1A | Skin corrosion/irritation Category 1A |
| Skin Irrit. 2 | Skin corrosion/irritation Category 2 |
| STOT RE 1 | Specific target organ toxicity (repeated exposure) Category 1 |
| STOT SE 3 | Specific target organ toxicity (single exposure) Category 3 |
| H280 | Contains gas under pressure; may explode if heated |
| H290 | May be corrosive to metals |
| H301 | Toxic if swallowed |
| H302 | Harmful if swallowed |
| H312 | Harmful in contact with skin |
| H314 | Causes severe skin burns and eye damage |
| H315 | Causes skin irritation |
| H318 | Causes serious eye damage |
| H319 | Causes serious eye irritation |
| H331 | Toxic if inhaled |
| H335 | May cause respiratory irritation |

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

| | | |
|---|-------------------------------------|-------------------------------|
| SDS Title: Gemcitabine for Injection Safety Data Sheet | SDS Number: SDS-000008 | Page Number: Page 11 of 11 |
| Function: Regulatory Affairs | Effective Date: October 03, 2018 | Version Number: 1.0 |

| | |
|------|--|
| 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 |
| H400 | Very toxic to aquatic life |
| H402 | Harmful to aquatic life |
| H411 | Toxic to aquatic life with long lasting effects |

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.

EFFECTIVE

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.