LKT Laboratories, Inc.

Safety Data Sheet

Section 1. Product and Company Identification

Product Name: Gemcitabine Hydrochloride
Product ID: G1745
Chemical Name (Synonyms): Gemzar
Supplier: LKT Laboratories, Inc
545 Phalen Blvd.
St. Paul, MN 55130 USA
Ph: 651-644-8424 Fax: 651-644-8357
www.lktlabs.com - getinfo@lktlabs.com
Emergency Phone #: 1-800-424-9300

Section 2. Hazards Identification

GHS Classification: Reproductive toxicity (Category 1B), H360

GHS Label elements including precautionary statements

Pictogram

Signal word: Danger

Hazard and precautionary statements

Hazard statement: H360 - May damage fertility or the unborn child.

Precautionary statements:
- P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P281 - Use personal protective equipment as required.
- P308 + P313 - IF exposed or concerned: Get medical advice/attention.
- P405 - Store locked up.
- P501 - Dispose of contents/container to an approved waste disposal plant.

HMIS Classification:
- Health hazard: 0
- Chronic health hazard: 0
- Flammability: 0
- Physical hazard: 0

NFPA Rating:
- Health hazard: 0
- Fire hazard: 0
- Reactivity hazard: 0

Potential Health Effects:
- Inhalation - May be harmful if inhaled. May cause respiratory tract irritation.
- Skin - May be harmful if absorbed through skin. May cause skin irritation.
- Eyes - May cause eye irritation.
Ingestion - May be harmful if swallowed. Reproduction: May damage fertility or the unborn child. Reproductive toxicity.

### Section 3. Composition/Information on Ingredients

<table>
<thead>
<tr>
<th>Substances</th>
<th>Ingredient: Title Compound</th>
<th>Percent: 100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formula</td>
<td>C₉H₁₁F₂N₃O₄ • HCl</td>
<td>Formula Wt.:  299.66</td>
</tr>
<tr>
<td>CAS No.</td>
<td>122111-03-9</td>
<td>EC No.</td>
</tr>
</tbody>
</table>

### Section 4. First Aid Measures

**General advice**
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

**Eye Contact**
Flush eyes with water as a precaution.

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

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

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

### Section 5. Firefighting Measures

**Flash Point**
Not available.

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

**Firefighting Procedures**
Wear self-contained breathing apparatus for fire fighting if necessary.

**Unusual Fire Hazards**
Not available.

### Section 6. Accidental Release Measures

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

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

**Methods and materials for containment and cleanup**
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

### Section 7. Handling and Storage

**Handling**
Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

**Storage Conditions**
Keep container tightly closed in a dry and well-ventilated place. Recommended storage temperature: Ambient Light sensitive. Store with desiccant.

**Hazardous Decomposition Products**
Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOₓ), hydrogen chloride gas, hydrogen fluoride.

**Other Remarks**
### Section 8. Exposure Controls/Personal Protection

**Personal protective equipment**

EXPOSURE CONTROLS

Contains no substances with occupational exposure limit values. Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

PERSONAL PROTECTION

Eye/face protection: Safety glasses with side-shields conforming to EN 166. 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. Full and Splash contact - Material: Nitrile rubber. Minimum layer thickness: 0.11 mm, Break through time: 480 min., Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M).

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).

### Section 9. Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid.</td>
<td>White crystal powder.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Solubility</th>
<th>Volatility</th>
<th>Ignition temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soluble in water, Slightly soluble in methanol, acetone, DMSO.</td>
<td>Not available.</td>
<td>Not available.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Boiling Point</th>
<th>Flash Point</th>
<th>Lower explosion limit</th>
<th>Upper explosion limit</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Water solubility</th>
<th>Partition coefficient: n-octanol/water</th>
<th>Relative vapor density</th>
<th>Odor Threshold</th>
<th>Evaporation rate</th>
</tr>
</thead>
</table>

### Section 10. Stability and Reactivity

**Stability**

Stable under recommended storage conditions.

**Materials To Avoid**

Strong oxidizing agents.

**Hazardous Decomposition Products**

Hazardous decomposition products formed under fire conditions. - Carbon oxides, nitrogen oxides (NOx), hydrogen chloride gas, hydrogen fluoride.
Section 11. Toxicological Information

**Oral LD50** Not available.

**Inhalation LC50** Not available.

**Dermal LD50** Not available.

**Other information on acute toxicity** Not available.

**Skin corrosion/irritation** Not available.

**Serious eye damage/irritation** Not available.

**Respiratory or skin sensitization** Not available.

**Germ cell mutagenicity** Not available.

**Carcinogenicity**
- 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.
- ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
- NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
- OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

**Reproductive Toxicity**
- Suspected human reproductive toxicant.
- Presumed human reproductive toxicant.

**Aspiration Hazard** Not available.

**Synergistic effects** Not available.

**Specific organ toxicity single exposure (GHS)** Not available.

**Specific organ toxicity repeated exposure (GHS)** Not available.

**Teratogenicity** Not available.

**Additional Information**
- Repeated dose toxicity: Mammal - Blood: Thrombocytopenia

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

**Potential Health Effects**
- Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.
- Skin: May be harmful if absorbed through skin. May cause skin irritation.
- Eyes: May cause eye irritation.
- Ingestion: May be harmful if swallowed.
- Reproduction: May damage fertility or the unborn child. Reproductive toxicity.

Section 12. Ecological Information

**Toxicity** Not available.

**Mobility in soil** Not available.

**PBT and vPvB assessment** PBT/vPvB assessment not available as chemical safety assessment not required/not
Section 13. Disposal Considerations

Waste Disposal
Dispose of material according to all federal, state, and local regulations. Offer material to a licensed, professional waste disposal company to dispose of as unused product.

Section 14. Transport Information

DOT (US) Not dangerous goods.
IATA Not dangerous goods.
IMDG Not dangerous goods.

Section 15. Regulatory Information

Reach No.

SARA 302 Components SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Components Chronic health hazard.

Massachusetts Right To Know Components No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components Gemcitabine hydrochloride 122111-03-9 Revision Date:

New Jersey Right To Know Components Gemcitabine hydrochloride 122111-03-9 Revision Date:

California Prop 65 Components This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Section 16. Other Information

Other information The information in this document is believed to be correct but is not necessarily complete. LKT does not guarantee the accuracy of the information. The burden of verifying the information in this document rests solely upon the user.