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

Material Name: Gemcitabine Hydrochloride for Injection
Trade Name: Not applicable
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: White to off-white Lyophilized powder
Signal Word: DANGER

Statement of Hazard:
May be harmful if swallowed.
Causes eye irritation.
Causes skin irritation.
May cause genetic defects.
May damage fertility or the unborn child.

Additional Hazard Information:
Short Term: May be absorbed through the skin and cause systemic effects.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system and blood and blood forming organs. Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects:
Adverse effects associated with therapeutic use include decreased blood cell count, nausea, vomiting, swelling, skin rash, liver enzyme changes, flu-like syndrome

EU Indication of danger:
Harmful
Irritant
Toxic to Reproduction: Category 2
Mutagenic: Category 2

EU Hazard Symbols:

EU Risk Phrases:
2. HAZARDS IDENTIFICATION

R22 - Harmful if swallowed.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R36/38 - Irritating to eyes and skin.

Australian Hazard Classification (NOHSC):

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gemcitabine hydrochloride</td>
<td>122111-03-9</td>
<td>Not Listed</td>
<td>Xn,R22; Xi, R36/38; Repr. Cat. 2, R60-61; Mut. Cat. 2, R46</td>
<td>51-53</td>
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<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C,R35</td>
<td>**</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>C,R35; T,R23</td>
<td>**</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Sodium hydroxide

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL / Limit (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Ceiling Threshold Limit</td>
<td>2</td>
</tr>
<tr>
<td>Australia PEAK</td>
<td>Listed</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>Listed</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
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<tr>
<td>Estonia OEL - TWA</td>
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<tr>
<td>France OEL - TWA</td>
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</tr>
<tr>
<td>Greece OEL - TWA</td>
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<tr>
<td>Hungary OEL - TWA</td>
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</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>Listed</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>Listed</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>Listed</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
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</tbody>
</table>

Revision date: 20-Jun-2011

Material Name: Gemcitabine Hydrochloride for Injection

Version: 1.0

Page 3 of 9
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls:
Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls:
Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:
Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:
Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:
Wear safety glasses or goggles if eye contact is possible.

Skin:
Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:
If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

Hydrochloric Acid
ACGIH Ceiling Threshold Limit: 2 ppm
Austria OEL - MAKs Listed
Belgium OEL - TWA Listed
Bulgaria OEL - TWA Listed
Cyprus OEL - TWA Listed
Czech Republic OEL - TWA Listed
Estonia OEL - TWA Listed
Germany - TRGS 900 - TWAs Listed
Germany (DFG) - MAK
Listed

Austria OEL - MAKs 2 ppm MAK
Belgium OEL - TWA 3.0 mg/m³ MAK
Bulgaria OEL - TWA Listed
Cyprus OEL - TWA Listed
Czech Republic OEL - TWA Listed
Estonia OEL - TWA Listed
Germany - TRGS 900 - TWAs
Listed

Gemcitabine hydrochloride
Pfizer Occupational Exposure Band (OEB):
OEB 5 - Skin (control exposure to <1ug/m³, provide additional precautions to protect from skin contact)
9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Lyophilized powder
Molecular Formula: Mixture
Water solubility: 15.3 g/L (gemcitabine)  
Partition Coefficient: 1.27 (gemcitabine)

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Mannitol
- Rat Oral LD 50 13500 mg/kg
- Mouse Oral LD 50 22 g/kg

Sodium hydroxide
- Mouse IP LD50 40 mg/kg

Gemcitabine hydrochloride
- Mouse Oral Minimum Lethal Dose 333 mg/kg
- Rat Oral LD50 > 500 mg/kg
- Rabbit Dermal LD50 > 1000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium hydroxide
- Eye Irritation Rabbit Severe
- Skin Irritation Rabbit Severe

Gemcitabine hydrochloride
- Skin Irritation Rabbit Irritant
- Eye Irritation Rabbit Irritant

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Gemcitabine hydrochloride
- 6 Month(s) Dog No route specified 0.04 mg/kg/day NOAEL Blood, Erythroid cells, Lymphoid tissue, Immune system
- 6 Month(s) Mouse No route specified 0.006 mg/kg/day LOAEL Erythroid cells, Male reproductive system, Spleen
11. TOXICOLOGICAL INFORMATION

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Gemcitabine hydrochloride
Reproductive & Fertility Mouse Intraperitoneal 0.05 mg/kg/day NOAEL Fertility
Fertility and Embryonic Development Mouse Intravenous 0.25 mg/kg/day LOAEL Fetotoxicity, Embryotoxicity, Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Gemcitabine hydrochloride
In Vivo Micronucleus Mouse Positive
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Positive
Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative
In Vivo Sister Chromatid Exchange Negative
In Vitro Chromosome Aberration Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Hydrochloric Acid
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Partition Coefficient (Calculated - Log Pow/Log Kow): 1.27 (gemcitabine)

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Gemcitabine hydrochloride
Onchorhynchus mykiss (Rainbow Trout) LC50 96 Hours > 1043 mg/L
Pimephales promelas (Fathead Minnow) LC50 96 Hours > 1014 mg/L
Daphnia Magna (Water Flea) EC50 48 Hours > 999 mg/L
Selenastrum capricornutum (Green Alga) EC50 5.4 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Gemcitabine hydrochloride
Nostoc sp. (Freshwater Cyanobacteria) MIC 800 mg/L
Aspergillus niger (Fungus) MIC > 1000 mg/L

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger:
Harmful
Irritant
Toxic to Reproduction: Category 2
Mutagenic: Category 2

EU Risk Phrases:
R22 - Harmful if swallowed.
R46 - May cause heritable genetic damage.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R36/38 - Irritating to eyes and skin.

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
DANGER
May be harmful if swallowed.
Causes eye irritation.
Causes skin irritation.
May cause genetic defects.
May damage fertility or the unborn child.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A

Sodium hydroxide
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>Listed</td>
<td>Listed</td>
<td>1.0% de minimis concentration acid aerosols including mists, vapor, gas, fog, and other airborne forms of any particle size</td>
<td>200-711-8</td>
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<tr>
<td>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</td>
<td>1000 lb final RQ</td>
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<td>2270 kg final RQ</td>
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<tr>
<td>CERCLA/SARA - Section 302 Extremely Hazardous TPQs</td>
<td>454 kg final RQ</td>
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<td>5000 lb final RQ</td>
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<td></td>
<td>Schedule 5</td>
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<td>500 lb TPQ gas only</td>
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Mannitol

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<th>Substance</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
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<td>EU EINECS/ELINCS List</td>
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Sodium acetate

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<th>Australia (AICS):</th>
<th>REACH - Annex IV - Exemptions from the obligations of Register:</th>
<th>EU EINECS/ELINCS List</th>
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<tbody>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<td>Australia (AICS):</td>
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<tr>
<td>CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs</td>
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<tr>
<td>EU EINECS/ELINCS List</td>
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</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

- R22 - Harmful if swallowed.
- R23 - Toxic by inhalation.
- R35 - Causes severe burns.
- R46 - May cause heritable genetic damage.
- R60 - May impair fertility.
- R61 - May cause harm to the unborn child.
- R36/38 - Irritating to eyes and skin.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by: Product Stewardship Hazard Communications
             Pfizer Global Environment, Health, and Safety Operations
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End of Safety Data Sheet