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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Cytarabine Sterile Powder

Trade Name: CYTOSAR; ARACYTINE; CYTOSAR-U
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: White to off-white crystalline powder
Signal Word: WARNING

Statement of Hazard: Suspected of damaging the unborn child.
Suspected of causing genetic defects.

Additional Hazard Information:
Short Term: May cause eye and skin irritation (based on components). Not acutely toxic (based on animal data).
Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Bone marrow suppression is the most serious adverse effect seen during clinical use. Adverse effects seen in clinical use include gastrointestinal discomfort, dizziness, and headache.

EU Indication of danger: Toxic to reproduction, Category 2
Mutagenic: Category 2

EU Hazard Symbols: T

EU Risk Phrases:
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.

2. HAZARDS IDENTIFICATION

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>Cytarabine</td>
<td>147-94-4</td>
<td>205-705-9</td>
<td>Mut. Cat.2;R46</td>
<td>~100</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat.2;R61</td>
<td></td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>C;R35</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>T;R23</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C;R35</td>
<td>**</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
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: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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

**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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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:** Avoid generating airborne dust. Avoid breathing dust. 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.

**Cytarabine**

- **Pfizer OEL TWA-8 Hr:** 2 µg/m³

**Hydrochloric Acid**

- **ACGIH Ceiling Threshold Limit:** 2 ppm
- **Australia PEAK**
  - 5 ppm
  - 7.5 mg/m³
- **Austria OEL - MAKs**
  - 5 ppm
  - 8 mg/m³
- **Belgium OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Bulgaria OEL - TWA**
  - 8.0 mg/m³
- **Cyprus OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Czech Republic OEL - TWA**
  - 8 mg/m³
- **Estonia OEL - TWA**
  - 5 ppm
  - 8 mg/m³
- **Germany - TRGS 900 - TWAs**
  - 2 ppm
  - 3 mg/m³
- **Germany (DFG) - MAK**
  - 2 ppm
  - 3.0 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Unit</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greece OEL - TWA</td>
<td>ppm</td>
<td>5</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>ppm</td>
<td>7</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>ppm</td>
<td>8</td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>ppm</td>
<td>5</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>ppm</td>
<td>7.5</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>ppm</td>
<td>5</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>ppm</td>
<td>8</td>
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<td>Luxembourg OEL - TWA</td>
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<td>Malta OEL - TWA</td>
<td>ppm</td>
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</tr>
<tr>
<td>Netherlands OEL - TWA</td>
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<tr>
<td>Poland OEL - TWA</td>
<td>ppm</td>
<td>5</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
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<tr>
<td>Slovakia OEL - TWA</td>
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</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>ppm</td>
<td>8</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>ppm</td>
<td>7.6</td>
</tr>
</tbody>
</table>

### Sodium hydroxide

**ACGIH Ceiling Threshold Limit:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Unit</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia PEAK</td>
<td>ppm</td>
<td>2</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>ppm</td>
<td>2</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>ppm</td>
<td>2.0</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>ppm</td>
<td>1</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>ppm</td>
<td>1</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>ppm</td>
<td>2</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>ppm</td>
<td>2</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>ppm</td>
<td>2</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>ppm</td>
<td>2</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>ppm</td>
<td>0.5</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>ppm</td>
<td>2</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>ppm</td>
<td>0.5</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>ppm</td>
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</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>ppm</td>
<td>2</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>ppm</td>
<td>1</td>
</tr>
</tbody>
</table>

### Analytical Method:

Analytical method available for cytarabine. Contact Pfizer Inc for further information.

### 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).
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Crystalline powder

Molecular Formula: Mixture

Solubility: Soluble: Water

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: There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.

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

Cytarabine
- Rat Oral LD 50 > 3000 mg/kg
- Rat Para-periosteal LD 50 > 5000 mg/kg
- Mouse Oral LD 50 3150 mg/kg
- Mouse Intravenous LD 50 > 7000 mg/kg

Sodium hydroxide
- Mouse IP LD50 40 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)

Cytarabine
- Eye Irritation Rabbit Minimal
- Skin Irritation Rabbit Mild

Hydrochloric Acid
- Skin Irritation Severe
- Eye Irritation Severe
11. TOXICOLOGICAL INFORMATION

Sodium hydroxide
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Severe

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

Cytarabine
Embryo / Fetal Development  Mouse  >= 2 mg/kg/day  LOAEL  Teratogenic
Embryo / Fetal Development  Rat  20 mg/kg  LOAEL  Teratogenic
Embryo / Fetal Development  Rat  50 mg/kg  LOAEL  Developmental toxicity
Embryo / Fetal Development  Mouse  8 mg/kg/day  LOAEL  Fetotoxicity

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

Cytarabine
In Vivo Chromosome Aberration  Rodent Bone Marrow  Positive
In Vivo Sister Chromatid Exchange  Rodent Bone Marrow  Positive
In Vivo Micronucleus  Mouse  Positive
In Vitro Chromosome Aberration  Human Lymphocytes  Positive
In Vitro  Human Lymphocytes  Positive

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Cytarabine
72 Week(s)  Rat  Oral  25 mg/kg/day  NOAEL  Not carcinogenic

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

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

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:**
- Toxic to reproduction, Category 2
- Mutagenic: Category 2

**EU Risk Phrases:**
- R46 - May cause heritable genetic damage.
- R61 - May cause harm to the unborn child.

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

**OSHA Label:**
**WARNING**
Suspected of damaging the unborn child.
Suspected of causing genetic defects.

**Canada - WHMIS: Classifications**

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

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**Cytarabine**
- California Proposition 65: developmental toxicity initial date 1/1/89
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 205-705-9

**Hydrochloric Acid**
- CERCLA/SARA 313 Emission reporting: 1.0 %
- CERCLA/SARA Hazardous Substances: 5000 lb
- and their Reportable Quantities: 2270 kg
- CERCLA/SARA - Section 302 Extremely Hazardous TPQs: 500 lb
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs</th>
<th>5000 lb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 5</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>231-595-7</td>
</tr>
</tbody>
</table>

**Water for Injection**

| Inventory - United States TSCA - Sect. 8(b)                       | Present |
| Australia (AICS):                                                 | Present |
| REACH - Annex IV - Exemptions from the obligations of Register:  | Present |
| EU EINECS/ELINCS List                                            | 231-791-2 |

**Sodium hydroxide**

<table>
<thead>
<tr>
<th>CERCLA/SARA Hazardous Substances and their Reportable Quantities:</th>
<th>1000 lb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>454 kg</td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
</tr>
<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 5</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>215-185-5</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.
R35 - Causes severe burns.
R23 - Toxic by inhalation.

**Data Sources:** Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection.

**Prepared by:** Product Stewardship Hazard Communication Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet