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

**Product Identifier**
- **Material Name:** Cytarabine Solution for Injection
- **Trade Name:** Cytosar; Aracytine; Ara-C
- **Chemical Family:** Mixture

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against**
- **Intended Use:** Pharmaceutical product used as Antineoplastic

**Details of the Supplier of the Safety Data Sheet**
- **Pfizer Inc**
  - Pfizer Pharmaceuticals Group
  - 235 East 42nd Street
  - New York, New York 10017
  - 1-800-879-3477
- **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
- International CHEMTREC (24 hours): +1-703-527-3887

**Contact E-Mail:** pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

**Classification of the Substance or Mixture**
- **GHS - Classification**
  - Germ Cell Mutagenicity: Category 1B
  - Reproductive Toxicity: Category 1B

**EU Classification:**
- 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.

**Label Elements**
- **Signal Word:** Danger
- **Hazard Statements:**
  - H340 - May cause genetic defects
  - H360D - May damage 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 attention/advice
- P405 - Store locked up
- P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Cytarabine Solution for Injection
Revision date: 30-Sep-2014

Other Hazards
Australian Hazard Classification (NOHSC):

No data available


Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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>GHS 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>Muta. 1B (H340)</td>
<td>2-10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr. Cat. 2; R60-61</td>
<td>Repr. 1B (H360D)</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.
Most Important Symptoms and Effects, Both Acute and Delayed
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.
Medical Conditions: None known
Aggravated by Exposure: None

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up
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.
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

Precautions for Safe Handling
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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
Refer to available public information for specific member state Occupational Exposure Limits.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Cytarabine

Pfizer OEL TWA-8 Hr: 2 µg/m³

Sodium chloride

Latvia OEL - TWA: 5 mg/m³
Lithuania OEL - TWA: 5 mg/m³


Exposure Controls

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.

Personal Protective Equipment:

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: Solution
Odor: No data available.
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available
Partition Coefficient: (Method, pH, Endpoint, Value)
Cytarabine

Sodium chloride

Water for Injection
No data available

Sodium chloride
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  Oxidizing Properties: No data available
  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
  Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: May cause eye and skin irritation (based on components).
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.

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  3150mg/kg
  Mouse  Intravenous  LD 50  > 7000mg/kg

Sodium chloride
  Rat  Oral  LD50  3000 mg/kg
  Mouse  Oral  LD50  4000 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

Sodium chloride
  Eye Irritation  Rabbit  Moderate
  Skin Irritation  Rabbit  Mild

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

Cytarabine
11. TOXICOLOGICAL INFORMATION

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

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Cell Type/Organism</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>In Vivo Chromosome Aberration</td>
<td>Rodent Bone Marrow</td>
<td>Positive</td>
</tr>
<tr>
<td>In Vivo Sister Chromatid Exchange</td>
<td>Rodent Bone Marrow</td>
<td>Positive</td>
</tr>
<tr>
<td>In Vivo Micronucleus</td>
<td>Mouse</td>
<td>Positive</td>
</tr>
<tr>
<td>In Vitro Chromosome Aberration</td>
<td>Human Lymphocytes</td>
<td>Positive</td>
</tr>
<tr>
<td>In Vitro Micronucleus</td>
<td>Human Lymphocytes</td>
<td>Positive</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>72 Week(s)</td>
<td>Rat</td>
<td>Oral</td>
<td>25 mg/kg/day</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
</tr>
</tbody>
</table>

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

12. ECOLOGICAL INFORMATION

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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

Cytarabine
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 developmental toxicity initial date 1/1/89
Australia (AICS): Present
Standard for the Uniform Scheduling of Drugs and Poisons: Schedule 4
EU EINECS/ELINCS List 205-705-9

Water for Injection
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
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 chloride
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 231-598-3

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3
Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
SAFETY DATA SHEET

Material Name: Cytarabine Solution for Injection
Revision date: 30-Sep-2014
Version: 3.0

Mutagenic: Category 2
Toxic to Reproduction: Category 2

R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.

Data Sources: Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 7 - Handling and Storage. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 15 - Regulatory Information. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 30-Sep-2014
Prepared by: Product Stewardship Hazard Communication

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