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

Product Identifier

Material Name: Cytarabine Sterile Powder

Trade Name: CYTOSAR; ARACYTINE; ARACYTIN; CYTOSAR-U; CYTARABINA

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

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

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

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
May form combustible dust concentrations in air
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

Other Hazards
Australian Hazard Classification (NOHSC):

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>Hazardous 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>~100</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>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>T; R23</td>
<td>STOT SE 3 (H335)</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C; R35</td>
<td>Skin Corr. 1A</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H314)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Press. Gas</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H331)</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C; R35</td>
<td>Skin Corr. 1A</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(H314)</td>
<td></td>
</tr>
</tbody>
</table>

<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>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</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 Aggravated by Exposure: None known

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: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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 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.

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
7. HANDLING AND STORAGE

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.

Conditions for Safe Storage, Including any Incompatibilities
Storage Conditions: Store as directed by product packaging.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
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.

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
      5 ppm
  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
  Greece OEL - TWA
      5 ppm
      7 mg/m³
  Hungary OEL - TWA
      8 mg/m³
  Ireland OEL - TWAs
      5 ppm
      8 mg/m³
  Italy OEL - TWA
      5 ppm
      8 mg/m³
  Japan - OELs - Ceilings
      5 ppm
      7.5 mg/m³
  Latvia OEL - TWA
      5 ppm
      8 mg/m³
  Lithuania OEL - TWA
      5 ppm
      8 mg/m³
  Luxembourg OEL - TWA
      5 ppm
      8 mg/m³
  Malta OEL - TWA
      5 ppm
      8 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Poland</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Romania</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Slovakia</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovenia</td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Spain</td>
<td>5 ppm</td>
</tr>
<tr>
<td>Switzerland</td>
<td>7.6 mg/m³</td>
</tr>
<tr>
<td>Vietnam</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

Sodium hydroxide

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Ceiling Threshold Limit:</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Australia PEAK</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>2.0 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>0.5 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

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:

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

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Crystalline powder</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble: Water</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
<tr>
<td>Cytarabine</td>
<td>No data available</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>No data available</td>
</tr>
<tr>
<td>Hydrochloric Acid</td>
<td>No data available</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability</td>
<td>Autoignition Temperature (Solid) (°C):</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Flammability (Solids):</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Flash Point (Liquid) (°C):</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
<tr>
<td></td>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
</tr>
<tr>
<td></td>
<td>No data available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>No data available</td>
</tr>
<tr>
<td>Chemical Stability</td>
<td>Stable under normal conditions of use.</td>
</tr>
<tr>
<td>Possibility of Hazardous Reactions</td>
<td></td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td>No data available</td>
</tr>
<tr>
<td>Conditions to Avoid</td>
<td>Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
<tr>
<td>Incompatible Materials</td>
<td>As a precautionary measure, keep away from strong oxidizers</td>
</tr>
<tr>
<td>Hazardous Decomposition Products</td>
<td>No data available</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information on Toxicological Effects General Information</td>
<td>There are no data for this formulation. The information included in this section describes the potential hazards of the individual ingredients.</td>
</tr>
<tr>
<td>Short Term</td>
<td>May cause eye and skin irritation (based on components). Not acutely toxic (based on animal data).</td>
</tr>
</tbody>
</table>
11. TOXICOLOGICAL INFORMATION

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 > 5000mg/kg
Mouse Oral LD 50 3150mg/kg
Mouse Intravenous LD 50 > 7000mg/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

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
11. TOXICOLOGICAL INFORMATION

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.

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
15. REGULATORY INFORMATION

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 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 and their Reportable Quantities:
  - 2270 kg
- CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs
  - 500 lb
- CERCLA/SARA - Section 302 Extremely Hazardous Substances:
  - 5000 lb
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
- EU EINECS/ELINCS List: 231-595-7

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 hydroxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - 454 kg
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
- EU EINECS/ELINCS List: 215-185-5
SAFETY DATA SHEET

Material Name: Cytarabine Sterile Powder
Revision date: 30-Sep-2014

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
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation
Acute toxicity, oral-Cat.3; H331 - Toxic if inhaled
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

Mutagenic: Category 2
Toxic to Reproduction: Category 2
T - Toxic
C - Corrosive

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.
Updated Section 2 - Hazard Identification.
Updated Section 3 - Composition / Information on Ingredients.
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 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