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

Product Identifier

Material Name: Cytarabine Injection, solution (Hospira, inc.)

Trade Name: Not established
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

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

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 Injection, solution (Hospira, inc.)
Revision date: 28-Jul-2017

Other Hazards
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytarabine</td>
<td>147-94-4</td>
<td>205-705-9</td>
<td>Muta. 1B (H340)</td>
<td>2-10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></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>*</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr. 1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>Hydrochloric acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Skin Corr. 1B (H314)</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3 (H335)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</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>*</td>
</tr>
</tbody>
</table>

Additional Information: * Proprietary
** to adjust pH

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 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

<table>
<thead>
<tr>
<th>Symptoms and Effects of Exposure:</th>
<th>For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Conditions</td>
<td>None known</td>
</tr>
<tr>
<td>Aggravated by Exposure:</td>
<td></td>
</tr>
</tbody>
</table>

Indication of the Immediate Medical Attention and Special Treatment Needed

| Notes to Physician: | None |

5. FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Extinguishing Media:</th>
<th>Extinguish fires with CO2, extinguishing powder, foam, or water.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Special Hazards Arising from the Substance or Mixture</td>
<td>Hazardous Combustion Formation of toxic gases is possible during heating or fire.</td>
</tr>
<tr>
<td>Products:</td>
<td>Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.</td>
</tr>
</tbody>
</table>

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal Precautions, Protective Equipment and Emergency Procedures</th>
<th>Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental Precautions</td>
<td>Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.</td>
</tr>
<tr>
<td>Methods and Material for Containment and Cleaning Up</td>
<td>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.</td>
</tr>
<tr>
<td>Additional Consideration for Large Spills:</td>
<td>Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.</td>
</tr>
</tbody>
</table>

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 | Store as directed by product packaging. 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

### SODIUM HYDROXIDE

- **ACGIH Ceiling Threshold Limit:** 2 mg/m³
- **Australia PEAK:** 2 mg/m³
- **Austria OEL - MAKs:** 2 mg/m³
- **Bulgaria OEL - TWA:** 2.0 mg/m³
- **Czech Republic OEL - TWA:** 1 mg/m³
- **Estonia OEL - TWA:** 1 mg/m³
- **France OEL - TWA:** 2 mg/m³
- **Greece OEL - TWA:** 2 mg/m³
- **Hungary OEL - TWA:** 2 mg/m³
- **Japan - OELs - Ceilings:** 2 mg/m³
- **Latvia OEL - TWA:** 0.5 mg/m³
- **OSHA - Final PELs - TWAs:** 2 mg/m³
- **Poland OEL - TWA:** 0.5 mg/m³
- **Slovakia OEL - TWA:** 2 mg/m³
- **Slovenia OEL - TWA:** 2 mg/m³
- **Sweden OEL - TWAs:** 1 mg/m³
- **Switzerland OEL - TWAs:** 2 mg/m³

### HYDROCHLORIC ACID

- **ACGIH Ceiling Threshold Limit:** 2 ppm
- **Australia PEAK:** 5 ppm
- **Austria OEL - MAKs:** 7.5 mg/m³
- **Belgium OEL - TWA:** 8 mg/m³
- **Bulgaria OEL - TWA:** 8 mg/m³
- **Cyprus OEL - TWA:** 5 ppm
- **Czech Republic OEL - TWA:** 8 mg/m³
- **Estonia OEL - TWA:** 8 mg/m³
- **Germany - TRGS 900 - TWAs:** 2 ppm
- **Germany (DFG) - MAK:** 3.0 mg/m³
- **Greece OEL - TWA:** 5 ppm
- **Hungary OEL - TWA:** 7 mg/m³
- **Ireland OEL - TWAs:** 8 mg/m³
- **Italy OEL - TWA:** 5 ppm
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWAs</th>
<th>OEL - TWA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Japan</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>8 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>5 ppm</td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>5 ppm</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 ppm</td>
<td>7.6 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 ppm</td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 ppm</td>
<td></td>
</tr>
</tbody>
</table>

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Sodium chloride

Pfizer Occupational Exposure Band (OEB):

Exposure Controls

Engineering Controls:
General room ventilation is adequate unless the process generates dust, mist or fumes. Engineering controls should be used as the primary means to control exposures. 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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands:
Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes:
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin:
Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Solution</th>
<th>Color:</th>
<th>Colorless</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available</td>
<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td>Cytarabine No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vapor Pressure (kPa):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vapor Density (g/ml):</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relative Density:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viscosity:</td>
<td>No data available</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Flammability:
- Autoignition Temperature (Solid) (°C): No data available
- Flammability (Solids): No data available
- Flash Point (Liquid) (°C): No data available
- Upper Explosive Limits (Liquid) (% by Vol.): No data available
- Lower Explosive Limits (Liquid) (% by Vol.): 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 > 5000mg/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

HYDROCHLORIC ACID
- Rat Oral LD 50 238-277 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
- 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
11. TOXICOLOGICAL INFORMATION

In Vivo Micronucleus  Mouse  Positive
In Vitro Chromosome Aberration  Human Lymphocytes  Positive
In Vitro  Human Lymphocytes  Positive

HYDROCHLORIC ACID
Bacterial Mutagenicity (Ames)  Salmonella  Negative
In Vivo Micronucleus  Rat  Negative

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.

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

Cytarabine

CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 developmental toxicity 1/1/1989
Australia (AICS): Present
Standard for the Uniform Scheduling for 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

SODIUM HYDROXIDE

CERCLA/SARA 313 Emission reporting Not Listed
CERCLA/SARA Hazardous Substances 1000 lb
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

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

CERCLA/SARA - Section 302 Extremely Hazardous: 5000 lb
Substances EPCRA RQs
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

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Data Sources: Publicly available toxicity information.
Reasons for Revision: New data sheet.
Revision date: 28-Jul-2017
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