



MATERIAL SAFETY DATA SHEET

Revision date: 14-Nov-2007

Version: 1.2

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

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

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Cytarabine Solution for Injection

| | |
|-------------------------|---|
| Trade Name: | Cytosar; Aracytine; Ara-C |
| Chemical Family: | Mixture |
| Intended Use: | Pharmaceutical product used as Antineoplastic |

2. HAZARDS IDENTIFICATION

Appearance: Colorless solution
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) . |
| 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:



EU Risk Phrases:

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

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

| Ingredient | CAS Number | EU EINECS/ELINCS List | Classification | % |
|-----------------|------------|-----------------------|-----------------------------------|------|
| Cytarabine | 147-94-4 | 205-705-9 | Mut. Cat.2;R46 Repr. Cat.2;R61 | 2-10 |
| Sodium chloride | 7647-14-5 | 231-598-3 | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | Classification | % |
|---------------------|------------|-----------------------|----------------|---|
| Water for Injection | 7732-18-5 | 231-791-2 | Not Listed | * |

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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.

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: Not applicable

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.

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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 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.

Storage Conditions: Store at 15-20 °C in properly labeled containers. Protect from light.

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

Sodium chloride

Latvia OEL - TWA = 5 mg/m³ TWA

Lithuania OEL - TWA = 5 mg/m³ IPRV

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.

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 | Color: | Colorless |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.

Conditions to Avoid: None known

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

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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)

Cytarabine

Rat Oral LD 50 > 3000 mg/kg
Rat Intravenous LD 50 > 5000 mg/kg
Mouse Oral LD 50 3150 mg/kg
Mouse Intravenous LD 50 > 7000 mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD 50 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

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

Sodium chloride

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

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

Cytarabine

Embryo / Fetal Development Mouse \geq 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

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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

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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:
S23 - Do not breathe fumes/vapour/spray.
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.

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Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Cytarabine

| | |
|---|-------------------------------|
| California Proposition 65 | Listed:Developmental Toxicity |
| Australia (AICS): | Present |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 4 |
| EU EINECS/ELINCS List | 205-705-9 |

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 chloride

| | |
|---|-----------|
| 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 mentioned in Section 3

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 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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