SAFETY DATA SHEET

Product Name: Cytarabine Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hospira Australia Pty Ltd 1 Lexia Place Mulgrave VIC 3170 AUSTRALIA
Emergency Telephone #'s	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418	
Hospira, Inc., Non-Emergency	224 212-2000	
Material Name	Cytarabine Injection	
Synonyms	4-amino-1-β-D-arabinofuranosyl-2(1H)-pyrimidinone; 1-β-D-Arabinofuranosylcytosine; 4-Amino-1-β-D-arabinofuranosylpyrimidin-2(1*H*)-one; Ara-C; Cytosar.	

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Cytarabine Injection is a solution containing cytarabine, a synthetic pyrimidine nucleoside anti-metabolite used in combination chemotherapy to treat some types of cancer. It is a cytotoxic agent. In the workplace, this preparation should be considered potentially irritating to the skin, eyes, and respiratory tract, a potential occupational reproductive hazard, and a potential human carcinogen. Based on clinical use, possible target organs may include the bone marrow, gastrointestinal tract, central nervous system, skin, eyes, and lungs.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Eye Damage/Irritation	2A
	Skin Corrosion/Irritation	2
	Toxic to Reproduction	2
	Germ Cell Mutagenicity	2
	STOT - RE	2

Label Element(s)

Pictogram

Signal Word Warning

Hazard Statement(s)

Causes serious eye irritation
Causes skin irritation
Suspected of damaging fertility or the unborn child
Suspected of causing genetic defects
May cause damage to organs through prolonged or repeated exposures

2. HAZARD(S) IDENTIFICATION: continued

Precautionary Statement(s)

Prevention

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not breathe vapors/spray.
Wash hands thoroughly after handling.

Response

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.

IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Cytarabine
Chemical Formula $C_9H_{13}N_3O_5$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Cytarabine	≤ 10	147-94-4	HA5425000

Non hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium chloride and/or benzyl alcohol; sodium hydroxide and/or hydrochloric acid may be added to adjust the pH.

4. FIRST AID MEASURES

Eye Contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability

None anticipated for this aqueous product.

Fire & Explosion Hazard

None anticipated for this aqueous product.

Extinguishing Media

As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures

No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal

Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling

Cytarabine is a cytotoxic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic antineoplastics agents to minimize potential exposures. Several guidelines on handling cytotoxic antineoplastic agents have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate. Consult your site hygienist or safety professional for your site requirements.

Avoid ingestion, inhalation, skin contact, and eye contact. When handling this product, precautions may include the use of a containment cabinet. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials is required when working with this material.

Storage

No special storage required for hazard control. However, employees should be trained on the proper storage procedures for antineoplastic agents. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions

No special precautions required for hazard control. Persons with known hypersensitivity to cytarabine, or who may be immune-compromised, women who are pregnant, or women who want to become pregnant, should consult a health and/or safety professional prior to handling open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Cytarabine	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

Respiratory Protection

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N99 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION: continued

Skin Protection	When handling this material, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to oncolytic agents. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.
Eye Protection	As a minimum, the use of chemical safety goggles is recommended when handling this material.
Engineering Controls	If the generation of aerosols is likely, local exhaust ventilation is recommended to minimize employee exposures. The use of an enclosure, such as an approved ventilated cabinet designed to minimize airborne exposures, is recommended.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear and colorless sterile isotonic solution
Odor	Odorless
Odor Threshold	NA
pH	7.4-7.6
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Soluble in water; slightly soluble in alcohol and chloroform
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Information for the product is not available. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Cytarabine	100	LD50	Oral	> 5000	mg/kg	Rat
Cytarabine	100	LD50	Oral	3150	mg/kg	Mouse
Cytarabine Hydrochloride	100	LD50	Oral	> 3200	mg/kg	Rat
Cytarabine Hydrochloride	100	LD50	Oral	826	mg/kg	Mouse
Cytarabine	100	LD50	Intravenous	> 5000	mg/kg	Rat
Cytarabine	100	LD50	Intravenous	> 7000	mg/kg	Mouse
Cytarabine Hydrochloride	100	LD50	Intravenous	172	mg/kg	Dog
Cytarabine Hydrochloride	100	LD50	Intravenous	396	mg/kg	Monkey
Cytarabine	100	LD50	Intraperitoneal	1000 > 5000	mg/kg mg/kg	Rat Rat
Cytarabine	100	LD50	Intraperitoneal	1000, 3379	mg/kg	Mouse
Cytarabine Hydrochloride	100	LD50	Intraperitoneal	5500	mg/kg	Rat
Cytarabine Hydrochloride	100	LD50	Intraperitoneal	825	mg/kg	Mouse

LD50 is the dosage producing 50% mortality.

Occupational Exposure Potential

There are scientific studies that suggest that personnel (e.g. nurses, pharmacists, etc.) who prepare and administer parenteral antineoplastics (e.g. in hospitals) may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these materials if workplace exposures are not properly controlled. The actual risk in the workplace is not known.

Signs and Symptoms

None anticipated from normal handling of this product. This material is irritating to the skin, eyes, and respiratory tract. In clinical use, adverse effects have included severe nausea and vomiting, bone marrow depression, rash and hair loss, pain and redness of the palms and feet, respiratory distress, and neurological effects such as ataxia, dysphasia, and nystagmus.

Aspiration Hazard

None anticipated from normal handling of this product.

Dermal Irritation/Corrosion

None anticipated from normal handling of this product. However, inadvertent skin contact with this product may produce irritation and redness.

Ocular Irritation/Corrosion

None anticipated from normal handling of this product. However, inadvertent eye contact with this product may produce irritation, with redness and tearing.

Dermal or Respiratory Sensitization

None anticipated from normal handling of this product. In clinical use, allergic edema has been reported infrequently.

Reproductive Effects

None anticipated from normal handling of this product. In animal studies, cytarabine was embryotoxic in mice and teratogenic in mice and rats when given during the period of organogenesis. In mice, cleft palate, phocomelia, deformed appendages, and skeletal abnormalities were noted in offspring of mice given intraperitoneal dosages ≥ 2 mg/kg/day during organogenesis. In rats, deformed appendages were noted in the offspring after dams were given cytarabine as a single intraperitoneal dosage of 20 mg/kg on day 12 of gestation. Reduced prenatal and postnatal brain size, and permanent impairment of learning ability, was noted in the offspring of rats given a single intraperitoneal dosage of 50 mg/kg on day 14 of gestation. In mice, cytarabine produced embryotoxicity, characterized by decreased fetal weight, when given at a dosage of 0.5 mg/kg/day during organogenesis; it also caused an increase in early and late resorptions, and decreased live litter sizes, at a dosage of 8 mg/kg/day. FDA Pregnancy Category D.

11. TOXICOLOGICAL INFORMATION: continued

Mutagenicity	Cytarabine was mutagenic in *in vitro* tests, and was clastogenic *in vitro* (chromosome aberrations and SCE in human leukocytes) and *in vivo* (chromosome aberrations and SCE assay in rodent bone marrow, mouse micronucleus assay). Cytarabine caused the transformation of hamster embryo cells and rat H43 cells *in vitro*. Cytarabine caused a dose-dependent increase in sperm-head abnormalities and chromosomal aberrations occurred in mice given intraperitoneal cytarabine.
Carcinogenicity	The carcinogenic potential of cytarabine has not been fully evaluated.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs may include the bone marrow, gastrointestinal tract, central nervous system, skin, eyes, and lungs.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product.
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt.
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not breathe vapors/spray.
Wash hands thoroughly after handling.

Response

If exposed or concerned: Get medical advice/attention. Get medical attention if you feel unwell.

IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes: NA

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
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