SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Cytarabine Injection**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 10, 2015
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Reproductive toxicity. Category 1A.
Germ cell mutagenicity. Category 2.
Eye Irritation. Category 2.
Skin Sensitization. Category 1.
Specific Target Organ Toxicity - STOT, Single Exposure SE. Category 3.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage fertility or the unborn child.
Suspected of causing genetic defects.
Causes serious eye irritation.
May cause an allergic skin reaction.
May cause respiratory irritation.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF exposed or concerned: Get medical advice/attention.
Call a POISON CENTER or doctor/physician if you feel unwell.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Store in a well-ventilated place. Keep container tightly closed.
Store locked up.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

- Eye: Contact with eyes may cause irritation.
- Skin: May cause skin irritation.
- Inhalation: May cause irritation of respiratory tract.
- Ingestion: May cause irritation.

Signs/Symptoms: Adverse events from therapeutic doses include: anorexia, nausea, vomiting, diarrhea, fever, rash, bleeding, mucosal inflammation, hepatic dysfunction, and thrombophlebitis. Other adverse events include: bone marrow suppression, anemia, leukopenia, thrombocytopenia, megaloblastosis, and reduced reticulocytes. Cellular changes in the morphology of bone marrow and peripheral smears can be expected. Infections may occur due to immunosuppression. A cytarabine syndrome has been described and is characterized by fever, myalgia, bone pain, chest pain, maculopapular rash, conjunctivitis, and malaise. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:	Individuals who are hypersensitive to cytarabine or have pre-existing bone marrow suppression.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Cytarabine	147-94-4	- %	
Water for Injection	7732-18-5	- %	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Protect from light. Retain in carton until time of use.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Freely soluble Slightly soluble in alcohol and chloroform.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	7.7
Molecular Formula:	Mixture
Molecular Weight:	243.22
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity:	Eye, skin, and respiratory irritation.
Cytarabine :	
Acute Toxicity:	Acute LD50 IP Rat: 1000 mg/kg Acute LD50 IP Mouse: 1000 mg/kg
Acute Effects:	Eye, skin, and respiratory irritation.
Teratogenicity:	Pregnancy Category D: Cytarabine may cause fetal harm if administered to a pregnant woman.
Cytarabine :	
RTECS Number:	HA5425000
Eye:	Eye - Human Standard Draize test.: 105 mg/7D (Intermittent)
Skin:	Administration onto the skin - Rat TDLo: 875 mg/kg/5W (Intermittent) [Endocrine - Changes in spleen weight Blood - changes in erythrocyte (RBC) count Blood - changes in leukocyte (WBC) count]
Ingestion:	Oral - Rat LD50: >5 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 3150 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: >5 gm/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: >7 gm/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Human TDLo: 17241 mg/kg/6D (intermittent) [Skin and Appendages - dermatitis,

allergic (after systemic exposure)]
Intravenous. - Rat TDLo: 90 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intravenous. - Rat TDLo: 360 mg/kg [Reproductive - Effects on Newborn - live birth index (measured after birth) Reproductive - Effects on Newborn - weaning or lactation index (e.g.,number alive at weaning per number alive at day 4)]
Intravenous. - Rat TDLo: 180 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death]
Intravenous. - Mouse TDLo: 45 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Effects on Newborn - live birth index (measured after birth)]
Intravenous. - Mouse TDLo: 18 mg/kg [Reproductive - Effects on Newborn - weaning or lactation index (e.g., number alive at weaning per number alive at day 4)]
Intravenous. - Mouse TDLo: 9 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intravenous. - Human Cytogenetic analysis: 239 mg/kg/5D
Intravenous. - Mouse DNA inhibition: 100 mg/kg
Intravenous. - Rabbit DNA inhibition: 50 mg/kg
Subcutaneous - Rat LD50: >5 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rat TDLo: 75 mg/kg [Reproductive - Effects on Newborn - stillbirth Reproductive - Effects on Newborn - viability index (e.g., number alive at day 4 per number born alive)]
Subcutaneous - Mouse Cytogenetic analysis: 315 mg/kg
Intraperitoneal. - Rat LD50: >5 gm/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 3779 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse TDLo: 40 mg/kg [Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse TDLo: 300 mg/kg/5D (intermittent) [Blood - changes in bone marrow (not otherwise specified) Blood - changes in leukocyte (WBC) count Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intraperitoneal. - Mouse TDLo: 359.1 mg/kg/9D (intermittent) [Kidney/Ureter/Bladder - Kidney tumors Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Rat TDLo: 2000 mg/kg/5D (intermittent) [Brain and Coverings - other degenerative changes Behavioral - changes in motor activity (specific assay) Behavioral - alteration of classical conditioning]
Intraperitoneal. - Rat TDLo: 100 mg/kg [Reproductive - Effects on Embryo or Fetus - other effects to embryo]
Intraperitoneal. - Rat TDLo: 20 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 50 mg/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 30 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Intraperitoneal. - Rat TDLo: 7500 ug/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Mouse TDLo: 5 mg/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
Intraperitoneal. - Mouse TDLo: 60 mg/kg [Reproductive - Fertility - litter size (e.g. number fetuses per litter; measured before birth) Reproductive - Effects on Newborn - weaning or lactation index (e.g., number alive at weaning per number alive at day 4)]
Intraperitoneal. - Mouse TDLo: 5 mg/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Mouse TDLo: 25 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
Intraperitoneal. - Mouse TDLo: 33 mg/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)]
Intraperitoneal. - Mouse TDLo: 60 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System]
Intraperitoneal. - Mouse TDLo: 50 mg/kg [Reproductive - Effects on Newborn - live birth index (measured after birth) Reproductive - Effects on Newborn - viability index (e.g., number alive at day 4 per number born alive) Reproductive - Effects on Newborn - growth statistics (e.g.percent, reduced weight gain)]
Intraperitoneal. - Mouse TDLo: 80 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 60 mg/kg [Reproductive - Fertility - litter size (e.g. number fetuses per litter; measured before birth) Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Effects on Newborn - behavioral]
Intraperitoneal. - Rat TDLo: 250 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System]
Intraperitoneal. - Rat TDLo: 60 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Effects on Newborn - growth statistics (e.g.%, reduced weight gain) Reproductive - Effects on Newborn - behavioral]
Intraperitoneal. - Rat TDLo: 2500 mg/kg/7W (intermittent) [Tumorigenic - equivocal tumorigenic agent by RTECS criteria Blood - lymphoma, including Hodgkin's disease Skin and Appendages - tumors]
Intraperitoneal. - Mouse TDLo: 4836 mg/kg/26W (intermittent) [Tumorigenic - equivocal tumorigenic agent by RTECS criteria Lungs, Thorax, or Respiration - tumors Blood - lymphoma, including Hodgkin's disease]
Intraperitoneal. - Mouse Micronucleus test: 2 mg/kg/24H
Intraperitoneal. - Mouse Unscheduled DNA synthesis: 100 mg/kg
Intraperitoneal. - Mouse DNA inhibition: 15 gm/kg
Intraperitoneal. - Mouse DNA inhibition: 25 mg/kg
Intraperitoneal. - Mouse Cytogenetic analysis: 200 ug/kg/24H (intermittent)
Intraperitoneal. - Mouse Sister chromatid exchange: 6400 ug/kg
Intraperitoneal. - Mouse Sperm Morphology: 6400 ug/kg
Intraperitoneal. - Mouse Micronucleus test: 6 mg/kg

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Cytarabine :

EINECS Number:	205-705-9
California PROP 65:	Listed: developmental.
Canada DSL:	Listed

Water for Injection :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1
HMIS Fire Hazard:	1
HMIS Reactivity:	1
HMIS Personal Protection:	X

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