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Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Fludarabine Phosphate for Injection, USP
Product Code: NDC 25021-205-05
Common/Trade Name: Fludara
Chemical Name: 9H-Purin-6-amine, 2-fluoro-9-(5-O-phosphono-β-D-arabinofuranosyl)
Chemical Family: Purine Nucleoside
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vials


Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	OSHA PEL	ACGIH TLV	Other Limits Recommended	CAS No.
Fludarabine Phosphate	2.5	None	None	None	75607-67-9
Mannitol	2.5	None	None	None	69-65-8
Sodium Hydroxide (for pH adj)	Trace	2mg/m ³	None	None	1310-73-2
Water for Injection	Balance	None	None	None	7732-18-5

Section 3 - Hazards Identification

Primary Physical and Health Hazards:

There is limited but increasing evidence that personnel involved in the preparation and administration of parenteral antineoplastics may be at some risk due to potential mutagenicity, teratogenicity, and/or carcinogenicity of these agents. The actual risk is not known. The US Pharmacopeia advisory panels recommend the cautious handling in both preparation and disposal of antineoplastic agents. Precautions that have been suggested include: use of a biological containment cabinet during reconstitution and dilution of parenteral medications, use of disposable surgical gloves and masks, use of proper technique to prevent contamination of medication onto the work area and operator, and proper disposal of needles, syringes, vials, and ampules.

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Routes of Entry: Inhalation, eye/skin contact, or ingestion

Signs & Symptoms of Exposure: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses are described in the package insert. Warnings include life-threatening and sometimes fatal autoimmune hemolytic anemia. Adverse effects include: myelosuppression, fever, chills, infection, nausea, vomiting, fatigue, pain, malaise, diaphoresis, alopecia, weakness, paresthesia, headache, cough, pneumonia, dyspnea, diarrhea, anorexia, stomatitis, rash, dysuria, edema, and myalgia.

There are clear, dose-dependent toxic effects seen with fludarabine. High doses of fludarabine phosphate have been associated with irreversible central nervous system toxicity characterized by delayed blindness, coma, and death. High doses are also associated with severe thrombocytopenia and neutropenia due to bone marrow suppression. There is no known specific antidote for fludarabine phosphate overdosage. Treatment consists of drug discontinuation and supportive therapy.

Fludarabine in combination with pentostatin (deoxycoformycin) for the treatment of refractory chronic lymphocytic leukemia (CLL) has been associated with a high incidence of fatal pulmonary toxicity in clinical trials, therefore, the use of fludarabine in combination with pentostatin is not recommended.


Occupational exposure has not been fully investigated.

Chemical Listed as Carcinogen: **NTP:** No **IARC:** No **OSHA:** No

Medical Conditions Generally Aggravated by Exposure: Individuals with hypersensitivity to Fludarabine Phosphate Injection or any of its components.

Section 4 - First Aid Measures


Eye Exposure: If irritation or redness develops, move away from exposure into fresh air. Flush eyes with clean water. For direct contact, hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Seek medical attention.

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- Skin Exposure:** Remove contaminated clothing and shoes. Wash skin with soap and plenty of water. If irritation occurs, seek medical attention.
- Ingestion:** In the event of swallowing this substance, seek medical advice. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. DO NOT induce vomiting.
- Injection:** Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposure to the therapeutic doses of this product. See package insert for adverse reactions associated with therapeutic doses of this product. Seek medical attention.
- Inhalation:** Remove to fresh air immediately. Seek medical attention. When appropriate and trained in CPR, provide artificial respiration.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

Section 5 - Fire Fighting Measures

- Flash Point:** Not established
- Autoignition Temperature:** Not established
- Flammable Limits in Air:** Lower %: Not established
Upper %: Not established
- Flammable Limits:** Not established
- Extinguishing Media:** Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
- Special Fire Fighting Procedures:** Wear self-containing breathing apparatus and protective clothing to prevent inhalation and contact with skin and eyes.
- Unusual Fire/Explosion Hazards:** When heated to decomposition, toxic fumes may be emitted.

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Section 6 - Accidental Release Measures


- Spill:** Wear recommended personal protective equipment (See Section 8 – Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.
- Release to Air:** If aerosolized, reduce exposures by ventilating area. Clean up immediately.
- Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

- General Handling:** When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.
- Waste Disposal Method:** Place in a thick plastic hazardous waste disposal bag or leak-proof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE. Dispose of waste in accordance with all applicable Federal, State and local laws.
- Storage Conditions:** Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

- Respiratory Protection:** Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.
- Eye Protection:** Safety glasses or goggles recommended.
- Ventilation:** Handle product in a well ventilated area. Restrict handling to authorized personnel.
- Skin Protection:** Wear lab coat, gown or smock as appropriate

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Other Protective Equipment: Wear latex or nitrile gloves


Additional Exposure Precautions: Not established

Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Fludarabine Phosphate	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Sodium Hydroxide	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

Section 9 - Physical and Chemical Properties

Physical State:	Clear	Specific Gravity:	Approx to water
Appearance and Odor:	Solution	Evaporation Rate:	Approx to water
Boiling Point:	Approx. 100°C	Solubility in Water:	Soluble
Vapor Pressure:	Not established	pH:	7.1 – 8.2
Vapor Density:	Not established	Molecular Weight:	365.2

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Section 10 - Stability and Reactivity

Stability:	Stable under recommended storage conditions.
Incompatibility (Materials to avoid):	No conditions contributing to instability are known to exist.
Hazardous Decomposition:	Will not occur.
Hazardous Polymerization:	Will not occur.
Conditions to Avoid:	No conditions contributing to instability are known to exist.


Section 11 - Toxicological Information

Signs & Symptoms of Exposure & Overexposure: PREGNANCY CATEGORY D: Fludarabine may cause fetal harm when administered to pregnant women. There are no adequate and well-controlled studies in pregnant women.

See Section 3 – Hazards Identification for more information.

Acute Toxicity

Component	Type	Route	Species	Dosage
Fludarabine Phosphate	LD ₅₀	IV	Male Rat	910 mg/kg
Fludarabine Phosphate	LD ₅₀	IV	Female Rat	1050 mg/kg
Fludarabine Phosphate	LD ₅₀	IV	Male Mouse	1404 mg/kg
Fludarabine Phosphate	LD ₅₀	IV	Female Mouse	1235 mg/kg
Fludarabine Phosphate	LD ₅₀	IV	Mouse-combined	1321 mg/kg
Fludarabine Phosphate	LD ₅₀ (five daily doses)	IV	Male Mouse	593 mg/kg

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Fludarabine Phosphate	LD ₅₀ (five daily doses)	IV	Female Mouse	496 mg/kg
Fludarabine Phosphate	LD ₅₀ (five daily doses)	IV	Mouse-combined	542 mg/kg

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations


TSCA - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 - *Not on this list*

OSHA Substance Specific - *No*


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Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.
 1901 N. Roselle Rd, Suite 700
 Schaumburg, IL 60195
 847-908-1600

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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)