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Section 1 - Identification


- (a) **Product Identifier:** Fludarabine Phosphate for Injection, USP
- (b) **Product Code:** 25021-205
25021-237
- Common/Trade Name:** Fludara
- Chemical Name:** 9H-Purin-6-amine, 2-fluoro-9-(5-O-phosphono-β-D-arabinofuranosyl)
- Chemical Family:** Purine Nucleoside
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Vials
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification

- (a) **Classification:** Unknown

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Emergency Overview:	Harmful or fatal if swallowed, inhaled or absorbed through skin. Overexposure may cause damage to the bone marrow, nervous and the male reproductive systems. May cause birth defects. Avoid breathing dust. Avoid contact with eyes, skin and clothing. Avoid exposure during pregnancy. Do not taste or swallow. Wash thoroughly after handling.

- (d) **Unknown Acute Toxicity:** N/A

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Section 3 – Composition / Information on Ingredients

Fludarabine Phosphate for Injection – NDC 25021-205

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
9H-Purin-6-amine, 2-fluoro-9-(5-O-phosphono-β-D-arabinofuranosyl)	Fludarabine Phosphate	2.5% (w/v)	75607-67-9	N/A
(2R,3R,4R,5R)-Hexan-1,2,3,4,5,6-hexol	Mannitol	2.5% (w/v)	69-65-8	N/A
Sodium Hydroxide	Sodium Hydroxide (for pH adj)	Trace	1310-73-2	N/A
H ₂ O	Water for Injection	Balance	7732-18-5	N/A

Fludarabine Phosphate Injection – NDC 25021-237

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
9H-Purin-6-amine, 2-fluoro-9-(5-O-phosphono-β-D-arabinofuranosyl)	Fludarabine Phosphate	5	75607-67-9	N/A
(2R,3R,4R,5R)-Hexan-1,2,3,4,5,6-hexol	D-Mannitol	5	69-65-8	N/A
Sodium Hydroxide	Sodium Hydroxide (for pH adj)	Trace	1310-73-2	N/A


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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.
- 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

- (a) **Extinguishing Media** Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
- (b) **Hazardous Combustion Products:** When heated to decomposition, toxic fumes may be emitted.
- (c) **Special Protective Equipment / Precautions:** Wear self-containing breathing apparatus and protective clothing to prevent inhalation and contact with skin and eyes.

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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:** Fludarabine phosphate for injection is a cytotoxic agent. All work practices must be designed to reduce human exposure to the lowest level.
- When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.
- Storage Conditions:** NDC 25021-205
Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).
- NDC 25021-237
Store in only approved containers, and keep away from incompatible materials. Store under refrigeration, between 2° and 8°C (36° to 46°F). Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

NDC 25021-205

Compound	Issuer	Type	Exposure Limit
Fludarabine Phosphate	OSHA	PEL	NE
	ACGIH	TLV	NE

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Compound	Issuer	Type	Exposure Limit
	-----	STEL	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Sodium Hydroxide	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

NDC 25021-237


Compound	Issuer	Type	Exposure Limit
Fludarabine Phosphate	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Sodium Hydroxide	OSHA	PEL	2mg/m ³
	ACGIH	TLV	NE
	-----	STEL	NE

(b) Engineering Controls

Ventilation: Handle product in a well ventilated area. Restrict handling to authorized personnel.

(c) Individual Protection Measures

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.
Skin Protection:	Wear lab coat, gown or smock as appropriate
Other Protective Equipment:	Wear latex or nitrile gloves

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Additional Exposure Precautions:	Not established
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Section 9 - Physical and Chemical Properties

(a)	Appearance	White Lyophilized Powder/Cake
(b)	Odor	No Odor
(c)	Odor Threshold	N/A
(d)	pH	7.2 – 8.2
(e)	Melting Point:	Not established
(f)	Initial Boiling Point:	N/A
(g)	Flash Point	N/A
(h)	Evaporation Rate:	N/A
(i)	Flammability	N/A
(j)	Upper Lower Flammability or Explosion Limits	N/A
(k)	Vapor Pressure @ 25°C:	N/A
(l)	Vapor Density:	N/A
(m)	Relative Density	N/A
(n)	Solubility(ies)	Soluble in water
(o)	Partition Coefficient: n-octanol/water	N/A
(p)	Auto-ignition Temperature	N/A
(q)	Decomposition Temperature	N/A
(r)	Viscosity	N/A

Section 10 - Stability and Reactivity

(a)	Reactivity	Not Reactive
(b)	Chemical Stability	Stable under recommended storage conditions.
(c)	Possibility of Hazardous Reactions	Hazardous polymerization will not occur
(d)	Conditions to Avoid	Avoid excessive heat.
(e)	Incompatible Materials	No conditions contributing to instability are

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		known to exist.
(f)	Hazardous Decomposition Products	Not available

Section 11 - Toxicological Information

This product is a cytotoxic and anti-neoplastic agent that may cause significant health effects from workplace exposure. The main expected routes of occupational exposure to this product are via inhalation of aerosols, eye and skin contact.

(a)	Likely Routes of Exposure	Inhalation, eye/skin contact, or ingestion
(b)	Symptoms related to the physical, chemical and toxicological characteristics	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.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

(d) 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
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

(e) Hazardous Chemical Listings

NTP: No

IARC: No

OSHA: No

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Section 12 - Ecological Information

(a)	Ecotoxicity	No applicable ecological information found.
(b)	Persistence and degradability	No applicable ecological information found.
(c)	Bioaccumulative potential	No applicable ecological information found.
(d)	Mobility in soil	No applicable ecological information found.
(e)	Other Adverse Effects	No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.


Section 14 - Transport Information

(a)	UN Number	Not Available
(b)	UN Proper Shipping Name	Not Available
(c)	Transport Hazard Class(es)	Not Available
(d)	Packing Group	Not Available
(e)	Environmental Hazards	Not Available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
(g)	Special Precautions	Not Available

DOT: Labels are not required.

ICAO/IATA: Not dangerous goods

IMDG: No component of this product is listed as a Marine Pollutant.

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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 – Not applicable
 CERCLA - Not applicable
 SARA 302 - Not applicable
 SARA 313 - Not applicable
 OSHA Substance Specific - No

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 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

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

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
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
DSL	Domestic Substances List

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EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMDG	International Maritime Dangerous Goods
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
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
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
SDS	Safety Data Sheet
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)
WHMIS	Workplace Hazardous Materials Information System