



Material Safety Data Sheet

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FLUDARABINE PHOSPHATE

Catalog Number: 1272204

Package Size: 300 mg

Revision Date:

April 22, 2003

EMERGENCY OVERVIEW - Reproductive Hazard. WARNING: As an antineoplastic agent, fludarabine phosphate is a possible carcinogen.

SECTION 1 - IDENTIFICATION

Common Name: Fludarabine Phosphate

Formula: C₁₀H₁₃FN₅O₇P

Synonym: n/f

Chemical Name: 9H-Purin-6-amine, 2-fluoro-9-(5-O-phosphono-beta-D-arabino furanosyl)-

CAS Number: 75607-67-9

RTECS Number: UO7440900

Chemical Family: Fluorinated adenine analog

Therapeutic Category: Antineoplastic

SECTION 2 - INGREDIENT INFORMATION

<u>Principle Components</u>	<u>Percent</u>	<u>Exposure Limits</u>
Fludarabine Phosphate	Pure Material	n/f

SECTION 3 - HEALTH HAZARD INFORMATION

Usual Adult Dose: Fludarabine phosphate is administered by intravenous infusion, 25 mg per square meter of body surface area a day for five days.

Adverse Effects: Adverse effects may include anemia, fever or chills, cough or hoarseness, lower back or side pain, painful or difficult urination, pain, shortness of breath, unusual bleeding or bruising, blood in urine or stools, pinpoint red spots on skin, swelling of feet or lower legs, agitation or confusion, blurred vision, loss of hearing, numbness or tingling, weakness, sores in mouth or on lips, diarrhea, nausea or vomiting, skin rash, unusual tiredness, aching muscles, headache, loss of appetite, and malaise. Possible allergic reaction to

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material if inhaled, ingested or in contact with skin.

Overdose Effects: High doses of fludarabine have been associated with a severe, delayed, and potentially fatal central nervous system toxicity including blindness, incontinence, seizures, deterioration of mental status, and coma.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization, bone marrow suppression, and cancer.

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation. Flush out mouth with water.

Medical Conditions Aggravated by Exposure:

Hypersensitivity to material, bone marrow depression, chickenpox (including recent exposure), herpes zoster, infection, impaired kidney function, and previous cytotoxic drug or radiation therapy.

Cross Sensitivity: n/f

Pregnancy Comments: Studies in rats and rabbits found dose-related birth defects, including external deformities and skeletal malformations. Antineoplastic therapy can affect male and female fertility.

Pregnancy Category: D

SECTION 4 - FIRST AID MEASURES

General: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

Overdose Treatment: n/f

SECTION 5 - TOXICOLOGICAL INFORMATION

Oral Rat: LD50: n/f

Oral Mouse: LD50: n/f

Irritancy Data: n/f

Target Organ(s): Bone marrow; central nervous system

Listed as a Carcinogen? NTP: No IARC: No OSHA: No

Other: Secondary malignancies are potential delayed effects of many antineoplastic agents, although it is not clear whether the effect is related to their mutagenic or immunosuppressive action. The effect of dose and duration of therapy is also unknown, although

SECTION 6 - FIREFIGHTING MEASURES

Flash Point: n/f

Upper Flammable Limit: n/f

Auto-Ignition Temperature: n/f

Lower Flammable Limit: n/f

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

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SECTION 7 - PHYSICAL HAZARDS

Conditions to Avoid: Protect from light, heat, and moisture.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits toxic fumes of HF and NOx. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 8 - HANDLING / SPILL / DISPOSAL MEASURES

Handling: As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. Store in a desiccator in a refrigerator.

Spill Response: Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Wash spill site. Place spillage and all contaminated cleanup materials in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE.

Disposal: Place material in a thick plastic hazardous waste disposal bag or leakproof container and label it CAUTION: HAZARDOUS CHEMICAL WASTE. Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 9 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Ventilation: Recommended.

Gloves: Rubber

Eye Protection: Safety Goggles

Protective Clothing: Protect exposed skin.

SECTION 10 - PHYSICAL AND CHEMICAL PROPERTIES

NOTE: The data reported below is general information, and is not specific to the USP Reference Standard Lot provided!

Appearance and Odor: White crystalline powder.

Melting Point: >155° C (decomposes)

Solubility in Water: Soluble

Vapor Density: n/f

Boiling Point: n/f

Evaporation Rate: n/f

Specific Gravity: n/f

Reactivity in Water: n/f

Vapor Pressure: n/f

% Volatile by Volume: n/f