

# BEDFORD LABORATORIES

300 Northfield Road  
Bedford, OH 44146  
Telephone: (440) 232-3320  
-or- (800) 562-4797

## MATERIAL SAFETY DATA SHEET

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### Section I - IDENTITY

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**Common/Trade Name:** Sterile Cytarabine, USP (100mg, 500mg, 1g or 2g/vial as lyophilized powder)

**Chemical Names:** 1- $\beta$ -D-Arabinofuranosylcytosine

**Synonyms:** Cytarabine, ara-C

**Manufacturer's Name:** BEN VENUE LABORATORIES, INC.

**Address:** 300 NORTHFIELD ROAD  
BEDFORD, OH 44146

**Emergency Telephone Number:** Chemtrec: 1(800)424-9300

**Telephone Number for Info.:** (440)232-3320 or (800)562-4797

**Medical Emergency:** Professional Services 1(800)521-5169

**Date Prepared:** April 20, 1996

**Date Revised:** October 27, 1999

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### Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

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<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Cytarabine	100	147-94-9	NONE	NONE	NONE

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### Section III - HEALTH HAZARD DATA

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**ROUTE(S) OF ENTRY:** Cytarabine is a toxic chemotherapy drug and may be absorbed via inhalation and ingestion.

**Health Hazard (Acute & Chronic):** Acute, excessive exposure may cause a variety of systemic effects in the blood forming systems, central nervous system, circulatory system, and digestive system. Chronic exposure may cause secondary malignancies.

**Carcinogenicity:** NTP? NO IARC Monographs? NONE Cytarabine is a potential mutagen, teratogen, and may cause secondary malignancies.  
OSHA Regulated? NO

**Signs & Symptoms of Exposure:** Signs of excessive exposure include anorexia, nausea, vomiting, diarrhea, oral and anal inflammation or ulceration, fever, rash and bleeding, sore throat, chest pain, dizziness, hair loss, shortness of breath and headache. May cause irritation to eyes and respiratory tract. May cause an allergic reaction.

**Medical Conditions**

**Generally Aggravated by Exposure:** Digestive and respiratory disorders

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#### Section IV - FIRST AID MEASURES

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**Eye Exposure:** Flush with large volumes of water for 15 minutes.

**Skin Exposure:** Wash with cool, soapy water for 15 minutes; remove contaminated clothing.

**Ingestion:** If ingestion occurs, flush mouth with water and seek medical attention from a physician immediately. If person is conscious, induce vomiting. Never induce vomiting on an unconscious person.

**Inhalation:** Remove to fresh air. If difficulty breathing, administer oxygen. Seek attention of a physician immediately. If necessary provide artificial respiration.

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#### Section V - FIRE AND EXPLOSION HAZARD DATA

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**Flash Point (Method Used):** Not Applicable      LEL: NA      UEL: NA

**Flammable Limits:** Not Applicable

**Extinguishing Media:** Use water or a type ABC multi-purpose extinguisher.

**Special Fire Fighting Procedures:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard concern.

**Unusual Fire/Explosion Hazards:** None

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#### Section VI - ACCIDENTAL RELEASE INFORMATION

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**Release to Land:** Wearing nitrile or latex gloves, lightly wet Cytarabine powder and absorb with a damp sorbent cloth. Dispose of according to local, state, and federal regulations.

**Release to Air:** If dust enters air, reduce exposures by ventilating the area, clean up the spill immediately. Wear respiratory protection.

**Release to Water:** Refer to local water authority. Drain disposal is not recommended; however, refer to local, state, and federal disposal guidelines.

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#### Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

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**Steps to be taken in case material is released or spilled:** See Section IV above. Wear double latex or nitrile gloves, safety glasses, and a respirator appropriate to protect against exposure to the airborne concentration.

**Waste Disposal Method:** Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

**Precautions to be taken in handling and storing:** Store vials at room temperature (15-30°C).

**Other Precautions:** Handle carefully. Follow OSHA guidelines on the safe handling of anti-cancer drugs. (See Section XVI.)

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## Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

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**Respiratory Protection:** If ventilation controls are unavailable, wear a half-mask, air purifying respirator with HEPA cartridges.

**Ventilation:** Handle product in a well-ventilated area or in a hood, glovebox, or biological safety cabinet.

**Protective Gloves:** Latex or nitrile gloves

**Eye Protection:** Safety glasses

**Other Protective Clothing or Equipment:** Necessary clothing to prevent skin contact such as a lab coat with a closed front, long sleeves, and elastic cuffs.

**Work/Hygienic Practices:** Wash hands following use. No eating, drinking, or smoking while handling product.

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## Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

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**Physical State:** Solid, white powder

**Appearance and Odor:** white, no odor

**Boiling Point:** Not Applicable

**Vapor Pressure:** Not Applicable

**Vapor Density:** Not Applicable

**Specific Gravity:** Not Applicable

**Melting Point:** 212-213°C

**Evaporation Rate:** Not Applicable

**Solubility in Water:** Freely soluble

**pH (when reconstituted):** 5

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## Section X - STABILITY AND REACTIVITY DATA

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**Stability:** Stable

**Conditions to Avoid:** Storage with oxidizers

**Incompatibility (Materials to Avoid):** Strong oxidizers

**Hazardous Decomposition or Byproducts:** When heated to decomposition temperatures greater than 212°C, toxic fumes or nitrogen oxides are emitted.

**Hazardous Polymerization:** Will not occur

**Conditions to Avoid:** None known

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## Section XI - TOXICOLOGICAL INFORMATION

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For Cytarabine

LD<sub>50</sub> oral, mouse = 3150 mg/kg

LD<sub>50</sub> intraperitoneal, mouse = 2700 mg/kg

LD<sub>50</sub> intravenous, mouse = 7000 mg/kg

LD<sub>50</sub> oral, rat = >500mg/kg

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## Section XII - ENVIRONMENTAL IMPACT INFORMATION

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No information is available.

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**Section XIII - DISPOSAL INFORMATION**

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Dispose of by incineration at an approved/permitted incinerator.  
Review local/state and federal regulations for your regulatory area.

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**Section XIV - TRANSPORTATION INFORMATION**

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Sterile Cytarabine USP is not a DOT Hazardous Material.  
Sterile Cytarabine USP is not a DOT Marine Pollutant.

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**Section XV - REGULATORY INFORMATION**

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SARA 313 listed?: NO  
CERCLA listed?: NO  
RCRA listed?: NO

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**Section XVI - OTHER DATA**

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1. Use of this product should be through or under the direction of a physician.  
This MSDS does not address the therapeutic use of this material.
2. Hospital personnel preparing or administering parenteral antineoplastic agents should wear disposable latex gloves, safety glasses, a closed-front gown with cuffs and respiratory protection. Preparation of all antineoplastic agents should be done in a class II laminar flow hood or biological safety cabinet with exhaust air discharged external to the room environment. All needles, syringes, vials, and other equipment or disposable clothing that have contacted this agent should be segregated for incineration.

The information provided is believed to be complete and accurate. It is the users responsibility to use the information according to their application. Bedford Laboratories and Ben Venue Labs, Inc. assumes no additional liability or responsibility resulting from the use of or reliance on this information.