



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

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

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

Chemical Names: 1-β-D-Arabinofuranosylcytosine

Synonyms: Cytarabine, ara-C, Udicil, AC-1075, Alexan, Arabitin, NCI-C04728,

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

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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Cytarabine	100	147-94-4	NONE	NONE	2 mcg/m ³

Cytarabine is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

Section III - HEALTH HAZARD DATA

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

OSHA Regulated? NO

Cytarabine is a potential mutagen, teratogen, and may cause secondary malignancies.

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, and 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

BVL Hazard Category: 4

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes 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.

Section V - FIRE AND EXPLOSION HAZARD DATA

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 not expected to present a fire hazard concern.

Unusual Fire/Explosion Hazards: None

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Wearing nitrile or latex gloves, lightly wet Cytarabine powder and absorb with a Damp absorbent 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 (P100 HEPA Filters).

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

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

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, preferably an air purifying half-mask with HEPA cartridges (P100).

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.)

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: If ventilation controls are unavailable, wear a half-mask, air purifying respirator with HEPA (p100) cartridges. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Ventilation: Handle product in a glovebox, or Class B2 biological safety

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.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid, white powder **Specific Gravity:** Not Applicable

Appearance and Odor: white, no odor **Melting Point:** 212-213°C

Boiling Point: Not Applicable **Evaporation Rate:** Not Applicable

Vapor Pressure: Not Applicable **Solubility in Water:** Freely soluble

Vapor Density: Not Applicable **pH (when reconstituted):** 5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

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: Storage with oxidizers

Section XI - TOXICOLOGICAL INFORMATION

Cytarabine: RTECS # HA5425000

LD₅₀ oral, mouse = 3150 mg/kg

LD₅₀ intraperitoneal, mouse = 3779 mg/kg

LD₅₀ intravenous, mouse = 7000 mg/kg

LD₅₀ oral, rat = >500mg/kg

LD₅₀ intravenous, rat = >5 gm/kg

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Cytarabine. Handle in a manner that prevents spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

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

Section XIV - TRANSPORTATION INFORMATION

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

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO
CERCLA listed?: NO
RCRA listed?: NO
Listed on the California Proposition 65 as Code D
Listed on the Massachusetts Hazardous Substance List: Codes 2,4 F8 F9

Section XVI - OTHER DATA

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.
3. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.
4. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):
1 = Low Toxicity
2 = Moderate Toxicity
3 = Potent or Toxic
4 = Highly Potent or Toxic
5 = Extremely Potent or Toxic
5. OEL=Occupational Exposure Limit. An internal limit set by Ben Venue Laboratories for the recommended limit of employee exposure to airborne dusts or aerosols that should not be exceeded over an eight-hour time-weighted average.

6. Cytarabine is considered a Hazardous Drug as described in the [NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings](#). Employees who prepare or administer hazardous drugs or who work in areas where these drugs are used should follow specific handling guidelines in order to prevent exposure to these agents in the air or on work surfaces, clothing, or equipment.

7. **The Following Guidance Information is excerpted from the NIOSH Alert:**

Elements of a Hazardous Drug Handling Program include:

- Establishment and implementation of written policies and protocols to ensure the safe handling of oncolytic and/or potent drugs, including receipt of product.
- Training and education of employees on the recognition, evaluation and control of Hazardous Drugs
- Effective Planning and design of the workplace
- Use of best practice control measures and specialized equipment such as ventilated cabinets or isolators designed for worker protection
- Wearing recommended personal protective equipment
- An integrated health surveillance program that: includes the assessment and counseling of prospective employees before they commence any work involving oncolytic and/or potent drugs and related waste

8. **Published guidance on the handling and transport of cytotoxic drugs:**

NIOSH Alert – Preventing occupational exposures to antineoplastic and other hazardous drugs in health care settings

<http://www.cdc.gov/niosh/docs/2004-165/>

National Study Commission on Cytotoxic Exposure: Recommendation for handling Cytotoxic Agents:

<http://www.nih.gov/od/ors/ds/pubs/cyto/index.htm>

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