



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

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Floxuridine 500 mg freeze dried cake
Chemical Names: 2'-Deoxy-5-fluorouridine
Synonyms: 2'-Deoxy-5-fluorouridine 5-fluorouracil-2'-deoxyriboside, Deoxyfluoroundine, FUDR, NSC-27640
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: May 10, 2000
Date Revised: December 18, 2001
Date Revised: February 22, 2007
 Date Revised: July 13, 2007

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>
Floxuridine	100	50-91-9	NONE	NONE	0.5 mcg/m ³ (BVL OEL)

Floxuridine 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

Routes of Entry: Floxuridine may be absorbed through inhalation and ingestion.
Health Hazard (Acute & Chronic): Floxuridine is a cytotoxic anticancer drug used for treating gastrointestinal adenocarcinoma, metastatic to the liver. It affects the gastrointestinal, central nervous, blood forming systems, kidneys, liver, eyes and skin. May irritate eyes, skin, and/or respiratory tract. May cause allergic reaction.
Carcinogenicity: NTP? NO IARC Monographs? NONE
 OSHA Regulated? NO

Floxuridine has shown to be teratogenic, mutagenic and fetotoxic in animal studies. Floxuridine is a suspected cancer causing agent. It is an antimetabolite of the pyrimidine analog type. Antimetabolites have been shown to be carcinogenic in animals and may be associated with an increased risk of secondary cancers in humans. Floxuridine produces oncogenic changes and is mutagenic in animals.

Signs & Symptoms of Exposure: Product may cause gastrointestinal effects such as nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite. May cause headache, dizziness, drowsiness, fatigue and lack of muscular coordination. May also cause nosebleeds and nail changes/loss of nails.

Medical Conditions Generally Aggravated by Exposure: Digestive and respiratory disorders and previously existing cardiovascular, liver, kidney and blood 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 skin 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.

Treat overdose symptomatically and monitor blood hematology post exposure.

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 aqueous-based and 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 Floxuridine powder and absorb with a damp sorbent cloth. Dispose of according to local, state, and federal regulations.

Release to Air: If dust generated, 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.

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 appropriate to protect against exposure to the airborne concentration. A half-mask respirator with HEPA cartridges (P100) is recommended. For larger spills, additional chemical protective clothing such as coveralls, boots and self-contained breathing apparatus (SCBA) may be needed.

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 temp. 59°- 86° F (15-30°C).

Other Precautions: Handle carefully; follow OSHA guidelines for safe handling of cytotoxic drug products (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 cartridges (P100). Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard, 29 CFR 1910.134.

Ventilation: Use with adequate ventilation such as within a Class II Type B 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 Floxuridine.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Solid, white to off-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: 150-151°C

Evaporation Rate: Not Applicable

Solubility in Water: Freely soluble

pH (when reconstituted): 4.0 to 5.5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): None

Hazardous Decomposition or Byproducts: When heated to decomposition temperatures, carbon monoxide, carbon dioxide, oxides of nitrogen, and hydrogen fluoride are emitted.

Hazardous Polymerization: Will not occur

Conditions to Avoid: Dust accumulation, airborne dust, sources of ignition, and storage with oxidizers.

Section XI - TOXICOLOGICAL INFORMATION

For Floxuridine: RTECS # YU7525000

LD₅₀ oral, rat = 215 mg/kg

TD_{LO} parenteral, woman = 173mg/kg / 82W-intermittent

LD₅₀ oral, mouse = 147 mg/kg

TD_{LO} intravenous, human = 5mg/kg/14D-C

LD₅₀ intraperitoneal, rat = 1600mg/kg

LD₅₀ unreported, mouse = 550mg/kg

LD₅₀ intraperitoneal, mouse = 650mg/kg

Toxicity studies show non-irritating to eyes (rabbits) and slightly irritating to skin (rabbits). Additional reproductive health and toxicity 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

Minimal information is currently not available on the environmental impact of Floxuridine. Handle in a manner that prevents spills or releases to the environment. May produce mutagenic affects in animals.

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

Floxuridine is not a DOT Hazardous Material.
Floxuridine is not listed as a marine pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?: NO

CERCLA listed?: NO

RCRA listed?: NO

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. 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.

3. 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
4. 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.
5. Floxuridine 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.
6. **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

7. **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>

This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this MSDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this MSDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.