



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

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Flumazenil (0.1 mg/ml, 5 and 10 ml vials)

Chemical Names: 4H-Imidazo(1,5-a)(1,4)benzodiazepine-3-carboxylic acid, 8-fluoro-5,6-dihydro-5-methyl-6-oxo-, ethyl ester

Synonyms: Anexate®, Romizicon®, Lanexat ®

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>
Flumazenil	0.01	78755-81-4	NONE	NONE	20 ug/m ³ (BVL OEL)
Methylparaben	0.18	9-76-3	NONE	NONE	NONE
Propylparaben	0.02	94-13-3	NONE	NONE	NONE
Glacial Acetic Acid	0.01	64-19-7	10 ppm	10 ppm 15 ppm (STEL)	NONE
Edetate Disodium	0.01	6381-92-6	NONE	NONE	NONE
Sodium Chloride	0.90	7647-14-5	NONE	NONE	NONE
Water for Injection	98.87	7732-18-5	NONE	NONE	NONE

Sodium Hydroxide and Hydrochloric acid solutions for pH adjustment.
Flumazenil Injection is a sterile injectable liquid drug provided in a vial.

Section III - HEALTH HAZARD DATA

Routes of Entry: Flumazenil Injection may be absorbed via contact with skin or eyes, inhalation of aerosols or accidentally ingested. Under normal use with supervision of a physician, Flumazenil Injection presents little hazard.

Health Hazard (Acute & Chronic): Flumazenil Injection is indicated for the partial or full reversal of the sedative effects of benzodiazepines and affects the central nervous and circulatory systems. Minimal adverse effect should occur from routine handling of this product. Acute signs and symptoms of excessive exposure may cause irritation to eyes, skin and respiratory tract. May cause headache, rapid pulse rate, hallucinations, tremors, convulsions, seizures and changes in breathing rates. No known chronic adverse effects are indicated.

Medical Conditions Generally Aggravated by Exposure: This material should not be used by persons with hypersensitivity to benzodiazepines.

Carcinogenicity: NTP? NO **IARC Monographs?** NONE **OSHA Regulated?** NO

Signs & Symptoms of Exposure: Exposure can cause irritation to eyes, skin, and respiratory system, headache, rapid pulse rate, hallucinations, tremors, seizures and changes in breathing rates.

BVL Hazard Category: 3

BVL Occupational Exposure limit (OEL): 20 ug/m³

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes. Get medical attention if irritation or signs of exposure are noted.

Skin Exposure: Remove contaminated clothing, wash skin with water and soap for 15 minutes. Get medical attention if irritation or signs of exposure are noted.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.

Injection: In cases of accidental injection, wash and disinfect area, get medical attention.

Inhalation: If difficulty with breathing, remove from exposure, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

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

Flammable Limits: Not Applicable

Extinguishing Media: Use water or an 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: Heat of the fire could cause vials or syringes to burst.

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Absorb Flumazenil Injection with absorbent materials and dispose according to local, state, and federal guidelines.

Release to Air: If aerosolized, reduce exposures by ventilating area.

Release to Water: Refer to local water authority. Drain disposal is not recommended; 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 VI above.

Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

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 at controlled room temperature 15°-30°C (59°-86°F). Follow instructions provided in packaging.

Other Precautions: None identified.

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

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.

Ventilation: Handle product in a well-ventilated area.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses

Other Protective Clothing or Equipment: Lab Coat

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

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Liquid

Appearance and Odor: Clear odorless solution

Boiling Point: Approximate to water

Vapor Pressure: Approximate to water

Vapor Density: Approximate to water

Specific Gravity: Not applicable

Melting Point: Not applicable

Evaporation Rate: Not applicable

Solubility in Water: Soluble

pH: 3.9 – 4.1

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): None identified.

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include potentially hazardous byproducts such as oxides of nitrogen, carbon monoxide, carbon dioxide and hydrogen fluoride.

Hazardous Polymerization: Will not occur

Conditions to Avoid: None identified.

Section XI - TOXICOLOGICAL INFORMATION

For Flumazenil Injection (active ingredient) RTECS Number N12922170

LD₅₀ mouse, Intraperitoneal = 4 gm/kg
LD₅₀ mouse, Intravenous = 143 mg/kg
LD₅₀ mouse, Oral = 1300 mg/kg
LD₅₀ mouse, Subcutaneous = > 1 gm/kg
LD₅₀ rat, Intraperitoneal = 1360 gm/kg
LD₅₀ rat, Intravenous = 85 mg/kg
LD₅₀ rat, Oral = 4200 mg/kg
LD₅₀ rabbit, Oral = 2 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 Flumazenil Injection. Handle in a manner to prevent 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

Flumazenil Injection is not a DOT hazardous material.
Flumazenil Injection is not a DOT Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?:	NO
CERCLA listed?:	NO
RCRA listed?:	NO
TSCA Inventory	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. Flumazenil may be 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>

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