



MATERIAL SAFETY DATA SHEET

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FLUMAZENIL INJECTION, USP

SECTION 1. PRODUCT AND COMPANY INFORMATION

Product Name: Flumazenil Injection
Supplier: West-Ward Pharmaceuticals
401 Industrial Way West
Eatontown, NJ 07724
Phone (732 542 1191)
Fax (732 720 6220)

Technical Phone: (800 631 2174)

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

CAS No.	Description	% in final Product
78755-81-4	Flumazenil	0.01
99-76-3	Methylparaben	0.18
94-13-3	Propylparaben	0.02
64-19-7	Glacial Acetic Acid	0.01
6381-92-6	Edetate Disodium	0.01
7647-14-5	Sodium Chloride	0.90
7732-18-5	Water for Injection	98.87

Sodium Hydroxide and Hydrochloric acid solutions for pH adjustment.

Category: Benzodiazepine antagonist

SECTION 3. HAZARDS IDENTIFICATION, EMERGENCY OVERVIEW

Route of Entry: Inhalation, injection, eye/skin contact or ingestion

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.

Chemical List as

Carcinogen:

NTP: No

IARC: No

OSHA: No

BVL Hazard Category: 3

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



WEST-WARD

PHARMACEUTICALS

SECTION 4. FIRST AID MEASURES

- Eyes: Immediately flush eyes with water for at least 15 minutes. Seek medical attention.
- Skin: Remove from source of exposure, wash affected area with soap and water, seek 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.
- Ingestion: If ingestion occurs, flush mouth with water and seek medical attention immediately. Never induce vomiting on an unconscious person.

SECTION 5. FIRE AND EXPLOSION DATA

Fire and explosion Data

- Closed Cup Flash Point: N/A
- Open Cup Flash Point: N/A
- Fire Point: N/A
- Autoignition: N/A
- Lower Explosion Limit: N/A
- General Hazard: Not expected to support combustion.
- Fire Fighting Instructions: Evacuate personnel to safe area. Water spray, dry chemical or multi-purpose extinguisher. If possible contain and collect water used.
- Fire Fighting Equipment: Firefighters should wear protective clothing and self-contained breathing equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Clean Up: Wear recommended personal protective equipment. Use an inert absorbent material to clean affected area, and place in a properly labelled container for recovery or disposal. Prevent entry into waterways, sewers, drainage systems and poorly ventilated areas. No specific decontamination or detoxification procedures have been identified for this product. Dispose of materials according to the applicable federal, state and/ or local regulations.

SECTION 7. HANDLING AND STORAGE

- General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with product, A dust/mist respirator (N95) may be necessary.
- Storage Conditions: Store below 15-30° C (59-86° F).



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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: N/A

Personal Protective Equipment

Eye protection: Safety glasses.

Hand protection: Latex gloves.

Respiratory Protection: If aerosols are generated, a disposable dust/ mist respirator (N95).

Skin Protection: Labcoat.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form/ Appearance: Clear solution

Boiling Point/ Boiling Range: Approx to Water.

Melting Point/ Melting Range: N/A.

Freezing Point: Approx to Water.

Vapor Pressure: N/A.

Relative Vapor Density: N/A.

Percent Volatiles: N/A.

pH: 3.9-4.1

Molecular Weight: 303.29

Solvent Solubility: Soluble in water

SECTION 10. STABILITY AND REACTIVITY DATA.

Stability: Stable under most conditions

Conditions to Avoid: None identified.

Hazardous Polymerization: N/A

Hazardous Decomposition or By-products: May include hydrogen fluoride, Carbon and Nitrogen Oxides.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Compound	Type	Route	Species	Dosage
Flumazenil for injection.	LD50	Oral	Rat	4200 mg/kg
	LD50	IP	Rat	1360 gm/kg
	LD50	IV	Rat	85 mg/kg
	LD50	Oral	Mouse	1300 mg/kg
	LD50	IP	Mouse	4 gm/kg
	LD50	IV	Mouse	143 mg/kg
	LD50	Oral	Rabbitt	2 gm/kg

Other: 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 12. ECOLOGICAL INFORMATION

Information is currently not available on the environmental impact of Flumazenil. Handle in a manner to prevent spills or release to the environment.

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

UN/NA Number: N/A

US DOT Hazard Class: N/A

Proper Shipping Name: N/A

Shipping Label: N/A

SECTION 15. REGULATORY INFORMATION

U.S. Regulatory Information: not regulated.

SECTION 16. OTHER INFORMATION

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Use of this product should be through or under the direction of a physician.

This MSDS does not address therapeutic use of this material.

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.