



## MSDS: Flumazenil Injection USP, 0.1mg/mL

### Material Safety Data Sheet

**Manufacturer:** Strides Arcolab Ltd,  
Opposite to IIMB,  
Bilekahalli  
Bangalore – 560076  
India

**Contact Telephone:** 1 – 800 – 932 - 5676

**Email:** customer.service@akorn.com

### Section 1 - IDENTIFICATION

**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 ®

**Date Prepared:** October 09, 2008

### 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</u>
					<u>Recommended</u>
Flumazenil	0.01	78755-81-4	NONE	NONE	20 ug/m <sup>3</sup> (BVL OEL)
Methylparaben	0.18	99-76-3	NONE	NONE	NONE
Propylparaben	0.02	94-13-3	NONE	NONE	NONE
Glacial Acetic Acid	0.01	64-19-7	10 ppm	10 ppm	NONE
				15 ppm (STEL)	
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.

### 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 AID 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**

<b>Physical State:</b> Liquid	<b>Specific Gravity:</b> Not applicable
<b>Appearance and Odor:</b> Clear odorless solution	<b>Melting Point:</b> Not applicable
<b>Boiling Point:</b> Approximate to water	<b>Evaporation Rate:</b> Not applicable
<b>Vapor Pressure:</b> Approximate to water	<b>Solubility in Water:</b> Soluble
<b>Vapor Density:</b> Approximate to water	<b>pH:</b> 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. Reference: MSDS of Ben Venue laboratories dated June 8, 2006

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.