MSDS: Flumazenil Injection USP, 0.1mg/mL

Material Safety Data Sheet

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

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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

<table>
<thead>
<tr>
<th>Component</th>
<th>%</th>
<th>CAS#</th>
<th>OSHA PEL</th>
<th>ACGIH TLV</th>
<th>Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flumazenil</td>
<td>0.01</td>
<td>78755-81-4</td>
<td>NONE</td>
<td>NONE</td>
<td>20 ug/m³ (BVL OEL)</td>
</tr>
<tr>
<td>Methylparaben</td>
<td>0.18</td>
<td>99-76-3</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
</tr>
<tr>
<td>Propylparaben</td>
<td>0.02</td>
<td>94-13-3</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
</tr>
<tr>
<td>Glacial Acetic Acid</td>
<td>0.01</td>
<td>64-19-7</td>
<td>10 ppm</td>
<td>10 ppm</td>
<td>NONE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>15 ppm (STEL)</td>
</tr>
<tr>
<td>Edetate Disodium</td>
<td>0.01</td>
<td>6381-92-6</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>0.90</td>
<td>7647-14-5</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>98.87</td>
<td>7732-18-5</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td></td>
<td>and Hydrochloric acid solutions for pH adjustment.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flumazenil Injection</td>
<td></td>
<td>is a sterile injectable liquid drug provided in a vial.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other Limits
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

| Physical State: Liquid | Specific Gravity: Not applicable |
| Appearance and Odor: Clear odorless solution | Melting Point: Not applicable |
| Boiling Point: Approximate to water | Evaporation Rate: Not applicable |
| Vapor Pressure: Approximate to water | Solubility in Water: Soluble |
| Vapor Density: Approximate to water | 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.


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