

5879



WEST-WARD

Material Safety Data Sheet

Revision date: 1/19/2012
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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: Flumazenil Injection
 Product code: NDC 0641-6031-01 NDC 0641-6031-10 NDC 0641-6032-01 NDC 0641-6032-10
 Synonyms: None
 Chemical Family: Benzodiazepine receptor antagonist
 Product Type: Regulated Prescription Drug
 Container Information: 5 and 10 ml vials
 Product Use: Pharmaceutical.

Supplier:
 WEST-WARD PHARMACEUTICALS
 EATONTOWN, NJ 07724

Emergency telephone number: CHEMTREC: USA & Canada (800) 424-9300 OUTSIDE USA +1 703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Flumazenil 78755-81-4	0.01	None	None
Sodium Chloride 7647-14-5	<1	None	Xi; R38
Methyl Paraben 99-76-3	<0.5	None	None
Propyl Paraben 94-13-3	<0.5	None	None
Edetate Disodium 139-33-3	<0.5	None	None
Acetic Acid 64-19-7	<0.5	UN2588 (solid, toxic); UN2902 (liquid, toxic); UN2903 (liquid, toxic, flammable); UN3021 (liquid, flammable, toxic) UN2789 (glacial); UN2790 (solution)	C;R35 R10
Water 7732-18-5	>98	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: Irritation potential to skin, eyes, and mucous membranes.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal-use conditions.
 Gastrointestinal effects (may include nausea, upset stomach, and loss of appetite).

Ingestion: Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness).

Skin contact: May cause skin irritation.

Eye contact: May cause eye irritation.

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4. FIRST AID MEASURES

- Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
- Skin contact:** Wash contaminated skin with soap and water. Get medical attention if irritation develops.
- Ingestion:** Do not induce vomiting unless directed by a physician. Never give anything by mouth to an unconscious person. Get medical attention if symptoms appear.
- Eye contact:** In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
- Notes to physician:** See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

- Suitable extinguishing media:** Use foam or all purpose dry chemicals to extinguish.
- Special protective equipment for firefighters:** Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
- Specific methods:** No information available
- Flash point:** Not determined
- Autoignition temperature:** Not available
- Flammable limits in air-lower (%):** Not available
- Flammable limits in air-upper (%):** Not available

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions:** Follow all fire fighting procedures (Section 5). Use suitable protective equipment (Section 8).
- Environmental precautions:** No information available.
- Methods for cleaning up:** For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

- Handling:**
- Technical measures/precautions:** Avoid skin contact. Avoid eye contact. Wash thoroughly after handling.
- Storage:**
- Technical measures/storage conditions:** Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).
- Incompatible products:** No special restrictions on storage with other products.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Flumazenil 78755-81-4	None	None	None	None	None	None
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Methyl Paraben 99-76-3	None	None	None	None	None	None
Propyl Paraben 94-13-3	None	None	None	None	None	None
Edate Disodium 139-33-3	None	None	None	None	None	None
Acetic Acid 64-19-7	= 10 ppm TWA = 25 mg/m ³ TWA	None	None	= 10 ppm TWA	= 15 ppm STEL	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures: Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:

Respiratory protection:

Perform exposure monitoring for this product and its components to ensure that employees are not exposed to levels greater than applicable regulatory limits. If exposure levels exceed regulatory limits, implement a respiratory protection program including respiratory protection that is in compliance with OSHA 29 CFR 1910.134 (in the US) or equivalent regulation in other regions. Fire fighting requires the use of a self-contained breathing apparatus with full face piece and positive pressure mode.

Hand protection:

Use chemical resistant, impervious gloves.

Skin and body protection:

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, and disposable suits).

Eye protection:

Safety glasses. Goggles, face shield, or other full-face protection if potential exists for direct exposure to aerosols or splashes.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Liquid
Appearance:	Aqueous solution
Color:	Clear
Odor:	Not available.
pH:	3.5 - 4.5
Molecular weight:	Not available.
Boiling point/range:	Not available.
Melting point/range:	Not available.
Density:	Not available.
Vapor pressure:	Not available.
Evaporation rate:	Not available.
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Viscosity:	Not available.
% Volatile by Volume:	Not available.

Product name: Flumazenil Injection

10. STABILITY AND REACTIVITY

Stability: Stable under recommended storage conditions.

Polymerization: Not applicable

Hazardous decomposition products: Not available.

Materials to avoid: Not available.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Flumazenil 78755-81-4	Oral LD50 Rat = 4200 mg/kg Oral LD50 Mouse = 1300 mg/kg Intravenous LD50 Rat = 85 mg/kg Intravenous LD50 Mouse = 143 mg/kg
Sodium Chloride 7647-14-5	Inhalation LC50 Rat >42 gm/m ³ /1H Oral LD50 Rat = 3 gm/kg Oral LD50 Mouse = 4 gm/kg Dermal LD50 Rabbit >10 gm/kg
Methyl Paraben 99-76-3	Oral LD50 Mouse > 8 g/kg
Propyl Paraben 94-13-3	Oral LD50 Mouse = 6332 mg/kg
Edetate Disodium 139-33-3	Oral LD50 Rat = 2 gm/kg Oral LD50 Mouse = 2050 mg/kg
Acetic Acid 64-19-7	Oral LD50 Rat = 3310 mg/kg Inhalation LC50 Mouse = 5620 ppm/1H Dermal LD50 Rabbit = 1060 uL/kg Intravenous LD50 Mouse = 525 mg/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/kg

Acute toxicity: Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness, blurred vision). Irritation potential to skin, eyes and mucous membranes.

Chronic toxicity: No data is available on the product itself.

Carcinogenic effects: Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on the product itself.

Mutagenic effects: May be mutagenic at cytotoxic doses.

Reproductive toxicity: No impairment to fertility based on animal data. May be fetotoxic based on animal data. Key developmental milestones may be delayed based on animal data.

FDA Pregnancy Category C

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12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Microtox Eotoxicity Data
Flumazenil 78755-81-4	LC50 > 518 mg/l Daphnia.	None.	None.	None.
Sodium Chloride 7647-14-5	None.	None.	None.	None.
Methyl Paraben 99-76-3	None.	None.	None.	None.
Propyl Paraben 94-13-3	None.	None.	None.	None.
Edetate Disodium 139-33-3	None.	LC50 (96 hr) bluegill:159 mg/L: Static.	None.	None.
Acetic Acid 64-19-7	None.	LC50 (96 hr) fathead minnow:88 mg/L:Static, 18-22 °C.;LC50 (96 hr) bluegill sunfish:75 mg/L.;LC50 (24 hr) goldfish:423 mg/L.:	None.	= 8.8 mg/L EC50 Photobacterium phosphoreum
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available.

Bioaccumulation: No data available.

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products:

Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name: None
 UN Number: None
 DOT Packing Group: None
 DOT Hazard class: None

TDG (Canada):

TDG Proper shipping name: None
 TDG UN/NA Number: None
 TDG Packing Group: None
 TDG Hazard class: None

ADR/RID:

ADR Official Transport Name: None
 ADR Proper shipping name: None

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14. TRANSPORT INFORMATION

ADR UN/NA number: None
 ADR Hazard Class: None

ICAO / IATA:

IATA Proper shipping name: None
 IATA UN NUMBER: None
 IATA Primary Hazard: None
 IATA Packing group: None
 ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None
 IMDG Hazard Class and Division: None
 IMDG Packing Group: None
 IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List - The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS) This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Flumazenil	0.01	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	<1	Not Listed	Not Listed	Not Listed	Not Listed
Methyl Paraben	<0.5	Not Listed	Not Listed	Not Listed	Not Listed
Propyl Paraben	<0.5	Not Listed	Not Listed	Not Listed	Not Listed
Edetate Disodium	<0.5	Not Listed	Not Listed	Not Listed	Not Listed
Acetic Acid	<0.5	Not Listed	= 2270 kg final RQ = 5000 lb final RQ	Not Listed	Not Listed
Water	>98	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop 65:	Minnesota Right-To-Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Flumazenil	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Methyl Paraben	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Propyl Paraben	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Edetate Disodium	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Acetic Acid	Not Listed	Present	Not Listed	Toxic, Flammable	Present	environmental hazard	sn 0004
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List - This product does not comply with DSL

EU EINECS List - This product does not comply with EINECS

Risk Phrases:

NONE

Safety Phrases:

NONE

 Product name: Flumazenil Injection

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

Updated company name from Baxter to West-Ward. Updated NDC codes

Additional information:

Not Available.

Prepared by:

West-Ward Pharmaceuticals

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End of safety data sheet

Product name: Flumazenil Injection