



Material Safety Data Sheet

MSDS Number: 1087946
Revision date: 02/08/2005
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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1087946
Product name: Lorazepam Injection
Product code: NDC 10019-102-01, NDC 10019-102-10, NDC 10019-103-01, NDC 10019-103-10, NDC 10019-102-46, NDC 10019-103-46, NDC 10019-102-47, NDC 10019-103-47, NDC 10019-102-39, NDC 10019-102-37, NDC 10019-103-39, NDC 10019-103-37, NDC 60977-112-81, NDC 60977-112-01, NDC 60977-112-71, NDC 60977-112-02, NDC 60977-113-81, NDC 60977-113-01, NDC 60977-113-71, NDC 60977-113-02, NDC 10019-105-01, NDC 10019-105-02, NDC 10019-106-01, NDC 10019-106-02, NDC 10019-106-71, NDC 10019-106-44, NDC 10019-105-71, NDC 10019-105-44, NDC 0641-0570-40

Synonyms: Ativan® (Lorazepam) Injection, Lorazepam Injection (NOVAPLUS)
Chemical Family: Benzodiazepine
Product Type: Regulated Prescription Drug
Container Information: Single and multiple dose vials and Tubex® sterile cartridge-needle units.
Product Use: Anticonvulsant, Sedative

Supplier:
BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
(800) 422-9837 or (847) 948-4770

Emergency telephone number: PROSAR: USA (888) 990-0996 OUTSIDE USA (615)917-6114
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Polyethylene Glycol 25322-68-3	18-20	None	None
Propylene Glycol 57-55-6	>79	None	None
Lorazepam 846-49-1	0.2-0.4	None	None
Benzyl Alcohol 100-51-6	2	UN1986 (flammable, toxic); UN1987 (alcohol); UN3065 (alcoholic beverages)	Xn;R20/22

3. HAZARDS IDENTIFICATION

Emergency overview: Do not ingest. Avoid eye contact. Avoid skin contact. Central Nervous System depression.

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

Inhalation: Inhalation not likely under normal use conditions.

Ingestion: CNS effects. Gastrointestinal effects.

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Skin contact: May cause skin irritation.

Eye contact: May cause eye irritation.

4. FIRST AID MEASURES

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. Oxygen may be administered if breathing is difficult. Get medical attention if symptoms appear.

Skin contact: Wash contaminated skin with soap and water. Get medical attention if irritation develops.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. 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.

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: Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions: No information available.

Methods for cleaning up: If emergency personnel are unavailable, contain spilled material. 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: Wash thoroughly after handling.

Storage:
Technical measures/storage conditions: Keep container tightly closed. Protect from light. Store refrigerated. Follow Schedule IV controlled substance requirements.

Incompatible products: No special restrictions on storage with other products.

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:
Polyethylene Glycol 25322-68-3	None	None	None	None	None	None
Propylene Glycol 57-55-6	None	None	None	None	None	None
Lorazepam 846-49-1	None	None	None	None	None	None
Benzyl Alcohol 100-51-6	None	None	None	None	None	None

Engineering measures: No special containment is required. Provide general or local exhaust ventilation.

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 CFR1910.134 (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.

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: Not available.
Color: Colorless
Odor: No information available
pH: Not available.
Molecular weight: Not applicable
Boiling point/range: Not available.
Melting point/range: Not available.
Density: Not available.
Vapor pressure: Not available.
Evaporation rate: Not determined
Solubility: Soluble in water.
Partition coefficient (n-octanol/water): Not available.
Viscosity: Not available.
% Volatile by Volume: Not available.

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10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Polymerization:	Not applicable
Hazardous decomposition products:	Not available.
Materials to avoid:	Slightly reactive to reactive with oxidizing agents, reducing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Polyethylene Glycol 25322-68-3	Oral LD50 Rat = 28 gm/kg Oral LD50 Mouse = 34 gm/kg Dermal LD50 Rabbit >20 gm/kg
Propylene Glycol 57-55-6	Oral LD50 Rat = 20 gm/kg Oral LD50 Mouse = 22 gm/kg Dermal LD50 Rabbit = 20800 mg/kg
Lorazepam 846-49-1	Oral LD50 Rat = 4500 mg/kg Oral LD50 Mouse = 1850 mg/kg
Benzyl Alcohol 100-51-6	Oral LD50 Rat = 1230 mg/kg Oral LD50 Mouse = 1360 mg/kg Dermal LD50 Rabbit = 2 gm/kg

Acute toxicity:	Signs and symptoms of overexposure to benzodiazepines may include headache, nausea, vomiting, diarrhea, incontinence, low blood pressure, sedation, sleepiness, confusion, impaired coordination, diminished reflexes, and possibly coma.
Chronic toxicity:	Contains material which may cause damage to the following organs: skin, eye, lens or cornea. Target Organs: Nervous System.
Carcinogenic effects:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. Not carcinogenic at all dose levels evaluated based on animal data.
Mutagenic effects:	No data is available on the product itself.
Reproductive toxicity:	No impairment to fertility based on animal data. Considered fetotoxic. See patient package insert for additional information.
FDA Pregnancy Category	D

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Microtox Etotoxicity Data
Polyethylene Glycol 25322-68-3	None.	LC50 (24 hr) goldfish:>5000 mg/L. (PEG 200, 400, 800).:	None.	= 100,000 mg/L EC50 Photobacterium phosphoreum polymer unspecified
Propylene Glycol 57-55-6	> 10000 mg/L EC50 water flea	LC50 (24 hr) goldfish:>5000 mg/L.;;LC50 (48 hr) guppy:>10000 mg/L.:	None.	= 710 mg/L EC50 Photobacterium phosphoreum
Lorazepam 846-49-1	None.	None.	None.	None.
Benzyl Alcohol 100-51-6	= 23 mg/L EC50 water flea	LC50 (96 hr) fathead minnow:460 mg/L:Static, 18-22 °C.;LC50 (96 hr) bluegill:10 mg/L:Static.	None.	= 63.7 mg/L EC50 Photobacterium phosphoreum = 71.4 mg/L EC50 Photobacterium phosphoreum

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Follow Schedule IV controlled substance requirements.

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

ICAO / IATA:

IATA Proper shipping name: None
 IATA UN NUMBER: None
 IATA Primary Hazard: None

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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:
Polyethylene Glycol	18-20	Not Listed	Not Listed	Not Listed	Not Listed
Propylene Glycol	>79	Not Listed	Not Listed	Not Listed	Not Listed
Lorazepam	0.2-0.4	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	2	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:
Polyethylene Glycol	Not Listed	Present	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Propylene Glycol	Not Listed	Present	Not Listed	Flammable	Not Listed	Present	Not Listed
Lorazepam	developmental toxicity; initial date 7/1/90	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	sn 1135
Benzyl Alcohol	Not Listed	Present	Not Listed	Not Listed	Present	[present]	Not Listed

This product contains component(s) known to the State of California to cause cancer or reproductive/developmental harm.

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

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16. OTHER INFORMATION

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

New MSDS format. Additional product codes.

Additional information:

Not Available.

Prepared by:

Technology Resources, Baxter Healthcare Corporation

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End of safety data sheet:

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