



Material Safety Data Sheet

MSDS Number: 1087952
Revision date: 09/22/2005
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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1087952
Product name: Midazolam HCl Injection
Product code: NDC 10019-027-01, NDC 10019-027-02, NDC 10019-027-05, NDC 10019-027-10, NDC 10019-028-02, NDC 10019-028-05, NDC 10019-028-10, NDC 10019-028-36, NDC 10019-028-03, NDC 10019-028-37, NDC 10019-028-39, NDC 10019-027-37, NDC 10019-027-03, NDC 10019-027-36, NDC 10019-027-04, NDC 10019-027-39, NDC 0641-0018-02, NDC 0641-0019-01, NDC 0641-0019-02, NDC 10019-027-29

Synonyms: Midazolam Injection (Parenta)
Chemical Family: Benzodiazepine
Product Type: Regulated Prescription Drug
Container Information: 1 ml, 2 ml, 5 ml, and 10 ml vials

Product Use: Pharmaceutical.

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:
Midazolam Hydrochloride 59467-96-8	0.1-0.5	None	T
Edetate Disodium 139-33-3	<0.1	None	None
Sodium Chloride 7647-14-5	<1	None	Xi; R38
Benzyl Alcohol 100-51-6	1	UN1986 (flammable, toxic); UN1987 (alcohol); UN3065 (alcoholic beverages)	Xn;R20/22
Water 7732-18-5	>97	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: HARMFUL IF SWALLOWED. Central Nervous System depression. May cause eye and skin irritation.

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

Inhalation: Inhalation not likely under normal use conditions.

Ingestion: No specific hazards other than therapeutic 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: In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. 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. If large quantities of this material are swallowed, call a physician immediately.

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:	Not applicable.
Flash point:	Not determined
Autoignition temperature:	Not available
Flammable limits in air-lower (%):	Not available
Flammable limits in air-upper (%):	Not available

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Do not ingest. Keep container closed. Wash thoroughly after handling.

Storage:

Technical measures/storage conditions: Keep container tightly closed in a dry and well-ventilated place. Store between 15-30°C (59 to 86°F). Follow Schedule IV controlled substance requirements.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Keep unnecessary personnel away. Use suitable protective equipment (Section 8).

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.

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:
Midazolam Hydrochloride 59467-96-8	None	None	None	None	None	None
Edetate Disodium 139-33-3	None	None	None	None	None	None
Sodium Chloride 7647-14-5	None	None	None	None	None	None
Benzyl Alcohol 100-51-6	None	None	None	None	None	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 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
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Physical state:

Liquid

Appearance:

Not available.

Color:

Colorless to light yellow.

Odor:

Odorless

pH:

2.9 - 3.7

Molecular weight:

Not applicable

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.

10. STABILITY AND REACTIVITY

Stability: This product is stable.
Polymerization: Not available.
Hazardous decomposition products: Not available.
Materials to avoid: Slightly reactive with oxidizing agents.

11. TOXICOLOGICAL INFORMATION

Component	LD50s and LC50s
Midazolam Hydrochloride 59467-96-8	Oral LD50 Rat: 215 mg/kg; Intravenous LD50 Rat: 75 mg/kg; Intravenous LD50 Mouse: 50 mg/kg; Intramuscular LD50 Rat: >50 mg/kg; Intramuscular LD50 Mouse: >50 mg/kg
Edetate Disodium 139-33-3	Oral LD50 Rat = 2 gm/kg Oral LD50 Mouse = 2050 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
Benzyl Alcohol 100-51-6	Oral LD50 Rat = 1230 mg/kg Oral LD50 Mouse = 1360 mg/kg Dermal LD50 Rabbit = 2 gm/kg
Water 7732-18-5	Oral LD50 Rat: >50000 mg/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. Potential increased incidence of neoplasm based on chronic animal administration. See patient package insert for additional information.

Mutagenic effects: Not mutagenic in a standard battery of genetic toxicological tests.

Reproductive toxicity: No impairment to fertility based on animal data. Not considered fetotoxic based on animal data.

FDA Pregnancy Category D

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Microtox Ecotoxicity Data
Midazolam Hydrochloride 59467-96-8	None.	None.	None.	None.
Edetate Disodium 139-33-3	None.	LC50 (96 hr) bluegill: 159 mg/L:Static.	None.	None.
Sodium Chloride 7647-14-5	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
Water 7732-18-5	None.	None.	None.	None.

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
 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:
Midazolam Hydrochloride	0.1-0.5	Not Listed	Not Listed	Not Listed	Not Listed
Edetate Disodium	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	<1	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	1	Not Listed	Not Listed	Not Listed	Not Listed
Water	>97	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:
Midazolam Hydrochloride	developmental toxicity; initial date 7/1/90	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
Sodium Chloride	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	Not Listed	Present	Not Listed	Not Listed	Present	[present]	Not Listed
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	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 complies with EINECS

Risk Phrases:

NONE

Safety Phrases:

NONE

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: