



MATERIAL SAFETY DATA SHEET

Product Name: Midazolam Hydrochloride Injection 

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

**Manufacturer Name
And Address** Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

Note: Hospira, formerly the Hospital Products Division of Abbott Laboratories, was created as an independent company in May 2004.

**Emergency Telephone
Hospira, Inc.** CHEMTREC: 800 424-9300
224 212-2055

Product Name Midazolam Hydrochloride Injection, USP

Synonyms None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Midazolam Hydrochloride
Chemical Formula C₁₈H₁₄Cl₂FN₃

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Midazolam Hydrochloride	0.1-0.5	59467-96-8	N/A
Benzyl Alcohol	1	100-51-6	DN3150000
Water	98	7732-18-5	ZC0110000

3. HAZARD INFORMATION

Emergency Overview In clinical use, this material is used as a sedative. Possible target organs include the central nervous system, skin, fetus, and gastrointestinal tract.

**Occupational Exposure
Potential** Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms No signs or symptoms from occupational exposure are known. Clinical data suggest the following: sedation, sleep, cognitive dysfunction, incoordination, coma, rash, visual impairment.

**Medical Conditions
Aggravated by Exposure** Data suggest any preexisting ailments in the following organs: skin, central nervous system, liver, kidney, eyes, gastrointestinal system. Concurrent intake of depressants like alcohol. Concurrent use of medications.

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4. FIRST AID MEASURES

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic / supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability: Non-flammable.

Fire & Explosion Hazard: None

Extinguishing Media: Use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Absorb with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required.

Storage No special storage required for hazard control. For product protection store at controlled room temperature of 15-30°C (59-86°F).

Special Precautions Protect from freezing and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits		
	OSHA-PEL	ACGIH-TLV	Hospira EEL
Midazolam Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 2 mcg/m3 STEL: Not Established
Benzyl Alcohol	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: 44.2 mg/m3 STEL: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.

STEL: 15-minute Short Term Exposure Limit.

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Respiratory Protection	Respiratory protection is not needed during normal product use.
Skin Protection	If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.
Eye Protection	Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.
Engineering Controls	Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Clear, colorless to slight yellow solution
Odor	Not Applicable
Boiling Point	Approximately that of water (100 °C, 212 °F).
Freezing Point	Approximately that of water (0 °C, 32 °F).
Vapor Pressure	Not Applicable
Vapor Density (Air=1)	Not Applicable
Evaporation Rate	Not Applicable
Bulk Density	Approximately that of water (1.0)
Specific Gravity	Approximately that of water (1.0)
Solubility	Water
pH	2.5-4.2

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	Not Determined
Hazardous Decomposition Products	Not Determined
Hazardous Polymerization	Not Determined.

11. TOXICOLOGICAL INFORMATION:

Acute Toxicity – Oral:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Midazolam Hydrochloride	100	LD50	1600	mg/kg	Rats
Benzyl Alcohol	100	LD50	1040-3100	mg/kg	Animals

LD50 is the dosage producing 50% mortality.
Product contains between approximately 0.1-0.5% Midazolam.

Acute Toxicity – Dermal:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Benzyl Alcohol	100	LD50(sc)	2000	mg/kg	Rabbits

LD50 (sc) is the value for skin contact.

Acute Toxicity – Inhalation:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Benzyl Alcohol	100	LC50	2000	ppm	Rats

LC50 is the concentration in air that produces 50% mortality.

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Mutagenicity Negative in the Ames test, Mutagenic in Micronucleus assay.

Target Organ Effects In clinical use target organ effects include gastrointestinal tract, central nervous system, skin, and eyes.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity Not Available

13. DISPOSAL CONSIDERATIONS:

Waste Disposal Disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state, and local regulations.

14. TRANSPORTATION INFORMATION

DOT Not Regulated

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status Not Regulated

CERCLA Status Not Regulated

SARA Status Not Regulated

RCRA Status Not Regulated

PROP 65 (Calif.) Midazolam Hydrochloride is identified in the state of California to cause reproductive toxicity.

Notes: TSCA Toxic Substance Control Act
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
SARA Superfund Amendments and Reauthorization Act
RCRA US EPA, Resource Conservation and Recovery Act
Prop 65, California Proposition 65

16. OTHER INFORMATION:

MSDS Coordinator T. Straits MPH, CIH

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