



SAFETY DATA SHEET

Midazolam Hydrochloride Injection (Without Preservative)

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, Australian WorkSafe, Japanese Industrial Standard JIS Z 7250:2000, and European Directives

1. PRODUCT IDENTIFICATION

1.1 TRADE NAME (AS LABELED):

Midazolam Hydrochloride Injection (Without Preservative)

SYNONYMS:

None known

CAS#:

Mixture

1.2 PRODUCT USE:

Pharmaceutical product used as antianxiety agent

PRODUCT CODE:

1.3 MANUFACTURER'S NAME:

Alvogen, Inc.

ADDRESS:

10 Bloomfield Avenue, Bldg B, Pine Brook, NJ 07058

BUSINESS PHONE:

1-844-842-8672

FAX NUMBER:

1-973-807-1625

1.4 EMERGENCY PHONE NUMBER:

EMERGENCY PHONE #:

1-844-842-8672

COMPANY WEB SITE INFORMATION:

www.alvogen.us.com

1.5 PREPARATION INFORMATION:

DATE OF CURRENT REVISION:

May 9, 2017

DATE OF LAST REVISION:

New

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW:

Product Description: This product is a clear, colorless liquid with no odor.

Health Hazards: Common adverse effects include respiratory depression, changes in blood pressure, headache, lightheadedness, dizziness and drowsiness, and dry mouth. This compound can cross the placenta in pregnant women. Secreted in human breast milk.

Flammability Hazards: This product is non-flammable.

Reactivity Hazards: None known

Environmental Hazards: The Environmental effects of this product have not been investigated. Release of this product is not expected to have significant adverse effects in the aquatic environment.

US DOT SYMBOLS

Non-Regulated Material

CANADA (WHMIS) SYMBOLS

Complies with WHMIS 2015

EUROPEAN and (GHS) Hazard Symbols



Signal Word: **Danger!**

2.1 CLASSIFICATION OF SUBSTANCE OR MIXTURE IN ACCORDANCE WITH 29 CFR 1200 (OSHA HCS) AND THE EUROPEAN UNION DIRECTIVES:

This product does meet the definition of a hazardous substance or preparation as defined by 29 CFR 1910. 1200 AND the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

EU HAZARD CLASSIFICATION OF INGREDIENTS PER DIRECTIVE 1272/2008/EC:

EC# 261-774-5 This substance is not classified in the Annex VI of Directive 67/548/EEC

EC# 613-386-6 This substance is not classified in the Annex VI of Directive 67/548/EEC

EC# 231-132-9 This substance is classified in the Annex VI of Directive 67/548/EEC, Index# 011-001-00-0

EC# 231-55-7 This substance is not classified in the Annex VI of Directive 67/548/EEC

EC# 215-185-5 This substance is not classified in the Annex VI of Directive 67/548/EEC

EC# 231-791-2 This substance is not classified in the Annex VI of Directive 67/548/EEC

Substances not listed either individually or in group entries must be self classified.-

Component(s) Contributing to Classification(s)

All Ingredients

2.2 LABEL ELEMENTS:

GHS Hazard Classification(s):

Oral Toxicity Category 4

Skin Corrosion/Irritation Category C

Skin Irritant Category 2

Eye Irritant Category 2A

STOT SE Category 3



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Reproductive Toxicity Category 2

Hazard Statement(s):

H302: Harmful if swallowed
H314: Causes severe skin burns and eye damage
H317: May cause an allergic skin reaction
H332: Harmful if inhaled
H335: May cause respiratory irritation
H360D: May damage the unborn child
H362: May cause harm to breast-fed children

Precautionary Statement(s):

P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe dust/fume/gas/mist/vapors/spray
P263: Avoid contact during pregnancy/while nursing
P264: Wash skin after handling.

2.3 HEALTH HAZARDS OR RISKS FROM EXPOSURE:

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The most significant routes of exposure for this product are by injection, ingestion, inhalation and skin or eye contact.

ACUTE:

Common adverse effects include respiratory depression, changes in blood pressure, headache, lightheadedness, dizziness and drowsiness, and dry mouth. This compound can cross the placenta in pregnant women. Secreted in human breast milk.

CHRONIC: Use of this product may cause reproductive harm. Repeat-dose studies in animals have shown a potential to cause adverse effects on nervous system and liver.

TARGET ORGANS: Acute: Skin, Eyes, Respiratory System

Chronic: Reproduction, Liver, Nervous System

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Ingredients:	WT (mg/mL)	CAS#	EINECS #	GHS Hazard Classification(s)
Midazolam Hydrochloride	0.5 – 1.0	59467-70-8	261-774-5	H312: Acute Dermal Toxicity Cat 4, H361: Reproductive Toxicity Cat 2, H317: Skin Sensitization Cat 1, H332 Acute Inhalation Toxicity Cat 4
Disodium Edetate	Proprietary	6381-92-6	613-386-6	H302: Acute Oral Toxicity Cat 4, H332 Acute Inhalation Toxicity Cat 4
Sodium Chloride	Proprietary	7440-23-5	231-132-9	H314: Skin Corrosion/Irritation Cat 1B
Hydrochloric Acid	Proprietary	7647-01-0	231-595-7	H314: Skin Corrosion/Irritation Cat 1B, H335: STOT SE Cat 3
Sodium Hydroxide	To adjust pH	1310-73-2	215-185-5	H314: Skin Corrosion/Irritation Cat C
Water for Injection	To adjust to 1 mL	7732-18-5	231-791-2	Not Classified
Balance of other ingredients is less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).				

NOTE: This product has been classified in accordance with the hazard criteria of the 29CFR1200 and the SDS contains all the information required by the CFR, EU Directives and the Japanese Industrial Standard JIS Z 7250: 2000.

4. FIRST-AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES:

EYE CONTACT: If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Seek medical attention if irritation continues or blurred vision occurs.

SKIN CONTACT: If product contacts skin, wash skin thoroughly with soap and water after handling. Seek medical attention if irritation develops and persists.

INHALATION: If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

INGESTION: If product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: None known



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4.2 SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Common adverse effects include respiratory depression, changes in blood pressure, headache, lightheadedness, dizziness and drowsiness, and dry mouth. This compound can cross the placenta in pregnant women. Secreted in human breast milk.

Repeat-dose studies in animals have shown a potential to cause adverse effects on nervous system and liver.

4.3 RECOMMENDATIONS TO PHYSICIANS: Treat symptoms and eliminate overexposure.

5. FIRE-FIGHTING MEASURES

5.1 FIRE EXTINGUISHING MATERIALS:

Use fire extinguishing methods below:

Water Spray: Yes

Carbon Dioxide: Yes

Foam: Yes

Dry Chemical: Yes

Halon: Yes

Other: Any "C" Class

5.2 UNUSUAL FIRE AND EXPLOSION HAZARDS:

No known fire or explosion hazards

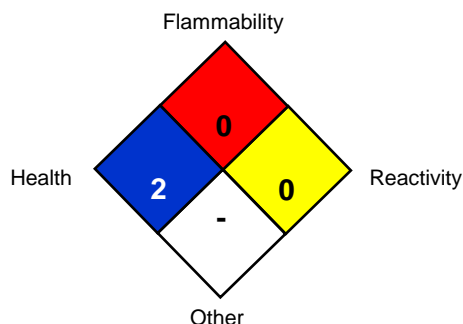
Explosion Sensitivity to Mechanical Impact: No

Explosion Sensitivity to Static Discharge: No



5.3 SPECIAL FIRE-FIGHTING PROCEDURES:

Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING SYSTEM



HMIS RATING SYSTEM

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM			
HEALTH HAZARD (BLUE)			2
FLAMMABILITY HAZARD (RED)			0
PHYSICAL HAZARD (YELLOW)			0
PROTECTIVE EQUIPMENT			
EYES	RESPIRATORY	HANDS	BODY
	See Sect 8		See Sect 8
For Routine Industrial Use and Handling Applications			

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

See section 8.2 for Exposure Controls.

6.2 ENVIRONMENTAL PRECAUTIONS:

None known

6.3 SPILL AND LEAK RESPONSE:

Absorb spill with absorbent material and place in an impervious container. Wash the contaminated area with an undiluted household or commercial sodium hypochlorite (bleach) solution. Dispose of in accordance with applicable Federal, State, and local procedures (see Section 13, Disposal Considerations).

7. HANDLING and STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING:

Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment Wash thoroughly after handling.



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7.2 STORAGE AND HANDLING PRACTICES:

Keep in cool, dry environment. Store at 20° to 25°C (68°F to 77°F). Protect containers from physical damage.

7.3 SPECIFIC USES:

Pharmaceutical product used as antianxiety agent

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

8.1 EXPOSURE PARAMETERS:

Chemical Name	CAS#	ACGIH TLV	OSHA TWA
Midazolam Hydrochloride	59467-70-8	Not Listed	Not Listed

8.2 EXPOSURE CONTROLS:

VENTILATION AND ENGINEERING CONTROLS: Not Applicable

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standard of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: Not normally required when using this product. If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

EYE PROTECTION Safety glasses should be worn when handling this product. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

SKIN PROTECTION: Gloves should be worn to prevent skin contact. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

9. PHYSICAL and CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

APPEARANCE (Physical State) and COLOR: This product is a clear, colorless liquid with no odor.

ODOR: None

ODOR THRESHOLD: Not Available

pH: Not Available

MELTING/FREEZING POINT: Not Available

BOILING POINT: Not Available

FLASH POINT: Not Applicable

EVAPORATION RATE (n-BuAc=1): Not Available

FLAMMABILITY (SOLID, GAS): Not Applicable

UPPER/LOWER FLAMMABILITY OR EXPLOSION LIMITS: Not Available

VAPOR PRESSURE (mm Hg @ 20°C (68°F): Not Available

VAPOR DENSITY: Not Available

RELATIVE DENSITY: Not Available

DENSITY: Not Available

SPECIFIC GRAVITY: Not Available

SOLUBILITY IN WATER: Not Available

WEIGHT PER GALLON: Not Available

PARTITION COEFFICIENT (n-octanol/water): Not Available

AUTO-IGNITION TEMPERATURE: Not Available

DECOMPOSITION TEMPERATURE: Not Available

VISCOSITY: Not Available

VOC g/l / Lb/gal: Not Available

9.2 OTHER INFORMATION:

No additional information available.



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10. STABILITY and REACTIVITY

10.1 REACTIVITY:

This product is not reactive.

10.2 STABILITY:

Stable under conditions of normal storage and use.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS:

Will not occur

10.4 CONDITIONS TO AVOID:

Incompatible materials

10.5 MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:

Strong oxidizers

10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

May emit toxic fumes.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

TOXICITY DATA:

Midazolam Hydrochloride CAS# 59467-70-8

Oral LD50 Rat: 215 mg/kg

SUSPECTED CANCER AGENT: None of the ingredients within this product are found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, or CAL/OSHA and therefore are not considered to be, or suspected to be, cancer-causing olam by these agencies.

IRRITANCY OF PRODUCT: This product may be irritating to eyes, skin and respiratory system.

SENSITIZATION TO THE PRODUCT: This product may contain ingredients considered to be respiratory system or skin sensitizers.

REPRODUCTIVE TOXICITY INFORMATION: This product contains an ingredient that may have adverse effects on the human reproductive system.

SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE: Eyes, Skin and Respiratory System

SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE: Reproduction, Liver, Nervous System

ASPIRATION HAZARD: None

12. ECOLOGICAL INFORMATION

12.1 TOXICITY:

No toxicity data available.

12.2 PERSISTENCE AND DEGRADABILITY:

No specific data available on this product.

12.3 BIOACCUMULATIVE POTENTIAL:

No specific data available on this product.

12.4 MOBILITY IN SOIL:

No specific data available on this product.

12.5 RESULTS OF PBT ANDvPvB ASSESSMENT:

No specific data available on this product.

12.6 OTHER ADVERSE EFFECTS:

No specific data available on this product.

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

12.7 WATER ENDANGERMENT CLASS:

Water endangering in accordance with EU Guideline 91/155-EWG. Not determined

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS:

Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Canada, Australia, EU Member States and Japan.

13.2 EU Waste Code:

Not determined



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14. TRANSPORTATION INFORMATION

US DOT, IATA, IMO, ADR:

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS: This product is classified (per 49 CFR 172.101) by the U.S. Department of Transportation, as follows.

14.1 PROPER SHIPPING NAME: Non-Regulated Material

14.2 HAZARD CLASS NUMBER and DESCRIPTION: None

14.3 UN IDENTIFICATION NUMBER: None

14.4 PACKING GROUP: None

14.5 DOT LABEL(S) REQUIRED: None

NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER: None

RQ QUANTITY: None

14.6 MARINE POLLUTANT: None of the components of this product are designated by the Department of Transportation to be Marine Pollutants (49 CFR 172.101, Appendix B).

14.7 SPECIAL PRECAUTIONS FOR USER:

Avoid exposure

14.8 INTERNATIONAL TRANSPORTION:

INTERNATIONAL AIR TRANSPORT ASSOCIATION SHIPPING INFORMATION (IATA): This product is not considered as dangerous goods.

INTERNATIONAL MARITIME ORGANIZATION SHIPPING INFORMATION (IMO): This product is not considered as dangerous goods.

14.9 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND IBC CODE:

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

15.1 UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: One or more of the components of this product are subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

SARA 302: Hydrochloric Acid CAS# 7647-01-0 TPQ 500 Lbs., Reportable Quantities 5000 Lbs., Sodium Hydroxide CAS# 7440-23-5 Reportable Quantities 1000 Lbs.

SARA 313 Reporting: Hydrochloric Acid CAS# 7647-01-0 1.0%

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for the components of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lbs (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITY (RQ): Hydrochloric Acid CAS# 7647-01-0 RQ 5000 Lbs, Sodium Hydroxide CAS# 7440-23-5 1000 Lbs

U.S. TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory or are exempted from listing. Commercial use of this material is regulated by the FDA.

OTHER U.S. FEDERAL REGULATIONS: None

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): Ingredients within this product are not on the Proposition 65 Lists.

15.2 CANADIAN REGULATIONS:

CANADIAN DSL/NDL INVENTORY STATUS: The components of this product are on the DSL Inventory, or are exempted from listing.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS:

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by those regulations.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: Complies with WHMIS 2015

15.3 EUROPEAN ECONOMIC COMMUNITY INFORMATION:

This product does meet the definition of a hazardous substance or preparation as defined by the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

See Section 2 for full Details.

15.4 AUSTRALIAN INFORMATION FOR PRODUCT:

The components of this product are listed on the International Chemical Inventory list.



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15.5 JAPANESE INFORMATION FOR PRODUCT:

JAPANESE MINISTER OF INTERNATIONAL TRADE AND INDUSTRY (MITI) STATUS:

The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

JAPANESE ENCS INVENTORY:

The components of this product are on the ENCS Inventory as indicated in the section on International Chemical Inventories, below.

POISONOUS AND DELETERIOUS SUBSTANCES CONTROL LAW:

No component of this product is a listed Specified Poisonous Substance under the Poisonous and Deleterious Substances Control Law.

16. OTHER INFORMATION

PREPARED BY: Paul Eigbrett – **(GHS MSDS Compliance PLUS)**

DATE OF PRINTING: May 9, 2017

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of the need that information is current, applicable and suited to the circumstances of use. Alvogen, Inc. assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, Alvogen, Inc. assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed.

END OF SDS SHEET