

Date Prepared: 08/06/1996  
Date Reviewed: 08/06/1996

**MIDAZOLAM HYDROCHLORIDE**

**1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

Product Identifier: Midazolam HCl

General Use: Anesthetic

**MANUFACTURER**

American Pharmaceutical Partners, Inc.  
1101 Perimeter Drive  
Schaumburg, IL 60173-5837  
(847) 969-2700

**EMERGENCY TELEPHONE NUMBER:**

(708) 450-7500

**2. COMPOSITION/INFORMATION ON INGREDIENTS**

Component: *Benzyl Alcohol*

CAS Registry #: 100-51-6

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: 1%

Note: To preserve

Component: *Edetate Disodium*

CAS Registry #: 139-33-3

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: 0.01%

Note: NA

Component: *Midazolam Hydrochloride*

CAS Registry #: 59467-96-8

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: 0.1% / 0.5%

Note: 1 mg/mL, 5 mg/mL

Component: *Sodium Chloride*

CAS Registry #: 7647-14-5

OSHA PEL: NE	mg/m3	OSHA PEL: NE	ppm
ACGIH TLV: NE	mg/m3	ACGIH TLV: NE	ppm
STEL: NE	mg/m3	STEL: NE	ppm

Percent of Product: 0.8%

Note: NA

**3. HAZARD IDENTIFICATION**

PRIMARY ROUTES OF EXPOSURE - Inhalation, Eye/Skin Absorption and Ingestion.

CHEMICAL LISTING AS CARCINOGEN BY CAS No.

CAS Nos: 59467-96-8,

National Toxicology Program: NO

IARC Monographs: NO

OSHA: NO

**COMPONENT**

Benzyl Alcohol

**CAS No.**

100-51-6

**NTP**

NO

**IARC**

NO

**OSHA**

NO

<u>COMPONENT</u>	<u>CAS No.</u>	<u>NTP</u>	<u>IARC</u>	<u>OSHA</u>
Edetate Disodium	139-33-3	NO	NO	NO
Midazolam Hydrochloride	59467-96-8			
Sodium Chloride	7647-14-5	NO	NO	NO

#### 4. EMERGENCY AND FIRST AID PROCEDURES

Inhalation: Move person to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

Ingestion: Flush mouth out with water immediately. Seek medical attention.

Skin Contact: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Seek medical attention.

Eye Contact: Immediately flush with water for at least 15 minutes. Seek medical attention.

For Adverse Drug Reaction Information call (708) 547-2372.

#### 5. FIRE FIGHTING MEASURES

Fire and Explosion Data:

Closed Cup Flash Pt. NE

Open Cup Flash Pt. NE

Fire Point NE

Autoignition NE

Lower Explosion Limit NE

Upper Explosion Limit NE

GENERAL HAZARD: When heated to decomposition it emits toxic fumes of F-, Cl- AND NOx.

FIRE FIGHTING INSTRUCTION: Water spray, dry chemical, carbon dioxide or foam as appropriate.

FIRE FIGHTING EQUIPMENT: Wear self-contained breathing apparatus and protective clothing.

HAZARDOUS COMBUSTION PRODUCTS: Smoke, and NOx fumes.

#### 6. ACCIDENTAL RELEASE MEASURES

CLEAN-UP: Wear recommended personal protective equipment. Use absorbent towels or booms to clean-up spill. Wipe surfaces clean and wash with soap and water.

#### 7. HANDLING AND STORAGE

When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Store product at room temperature 15 $\phi$ -30 $\phi$ C (59 $\phi$ -86 $\phi$ F) and in accordance with the regulations set forth in the Controlled Substance Act of 1970.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

General room ventilation is usually satisfactory, use local exhaust ventilation when necessary.

PERSONAL PROTECTION:

Respirators - With satisfactory ventilation, respiratory protection not usually required.

Eyes - Safety glasses or goggles recommended.

Gloves - Disposable latex gloves recommended.

Clothing - Disposable garments if direct skin contact is anticipated.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Odor other characteristics: Clear, colorless to light yellow solution.

Boiling Point: NA

Vapor Density: NA

Melting Point: ~-159°C(Raw Mat)

Percent Volatiles: NA

Freezing Point: NA

pH: ~3

Vapor Pressure: NA

Molecular Weight: 362.25

Note:

Solubility: SOLUBLE (as the HCl salt)

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## 10. STABILITY AND REACTIVITY

Stability - Stable.

Conditions/Materials to Avoid - None.

Hazardous Polymerization - Will not occur.

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## 11. TOXICOLOGY INFORMATION

SIGNS & SYMPTOMS OF OVEREXPOSURE MAY INCLUDE:

This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Occupational exposure has not been fully investigated.

MEDICAL CONDITIONS AGGRAVATED BY ACCIDENTAL EXPOSURE: Pre-existing skin and respiratory conditions.

Oral Rat LD50 = 1600 mg/Kg

-This value refers to 100% of raw midazolam.

IMMEDIATE EFFECTS: Eye, skin and respiratory irritation have been experienced with patient administration.

DELAYED EFFECTS:

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## 12. TRANSPORT INFORMATION

UN/NA Number: NA

DOT Hazard Class: NA

Shipping Name: NA

Shipping Label: NA

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## 13. WASTE DISPOSAL

Waste Disposal - Dispose of in accordance with federal, state and local regulations. Also in accordance with the Controlled Substance Act CFR 1307.21.

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## 14. OTHER INFORMATION

### KEY TO ABBREVIATIONS:

ACGIH - American Conference of Governmental Industrial Hygienists

HEPA - High-Efficiency Particulate Air

IARC - International Agency for Research on Cancer

NA - Not Applicable

NE - Not Established

NG - Not Given

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PEL - Permissible Exposure Limit

PPM - Parts Per Million

QS - Quantity Sufficient

RCRA - Resource Conservation and Recovery Act

STEL - Short Term Exposure Limit

TLV - Threshold Limit Value

The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. APP, Inc., assumes no liability resulting from the use of, or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specification of the product.

This product is classified as controlled substance and as such is subject to control under the Federal Controlled Substance Act of 1970 as a Schedule IV (C-IV) drug.

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