

MATERIAL SAFETY DATA SHEET

Midazolam HCl syrup 2 mg/mL

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SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: Midazolam HCl 2 mg/mL
COMMON NAME: Midazolam HCl 2 mg/mL
CHEMICAL NAME: 8-chloro-6(2-fluorophenyl)-1-methyl-4H-imidazo-[1,5a][1,4]-benzodiazepine hydrochloride
SYNONYMS: NA
CHEMICAL FORMULA: C₁₈H₁₃ClFN₃HCl
CHEMICAL FAMILY: Benzodiazepines

SECTION 2: COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	OSHA PEL	ACGIH TLV	IDLH
*Midazolam	59467-70-8	NE	NE	NE
Sorbitol Solution	50-70-04	NE	NE	NE
Glycerin, USP	56-81-5	15 mg/m ³	15 mg/m ³	NE
*Citric Acid	77-92-9	NE	NE	NE
*Sodium Citrate	68-04-02	NE	NE	NE
*Sodium Benzoate	532-32-1	NE	NE	NE
*Disodium EDTA Dihydrate	6381-92-6	NE	NE	NE
*Hydrochloric Acid	7647-01-0	5 mg/m ³	2 mg/m ³	NE
*D & C Red no. 33	3567-66-6	10 mg/m ³	10 mg/m ³	NE
*Mixed Fruit Flavor	N/A	NE	NE	NE
*Bitter Mask	N/A	NE	NE	NE
Purified Water, USP grade		NE	NE	NE

TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.

NE = Not Established, Specific amounts are considered proprietary information.

*These ingredients are at concentrations of less than 1%.

**Mixed Fruit Flavor and Bitter Mask are both mixtures and do not have a listed CAS#.

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: Midazolam HCl Syrup 2 mg/mL is a clear, red syrup with a fruity odor, free of particulate matter.

Symptoms of Overexposure by Route of Exposure: The potential for overexposure is reduced in the finished pharmaceutical form. Possible overexposure effects are sedation, somnolence, confusion, impaired coordination, diminished reflexes, coma.

SECTION 4: FIRST AID MEASURES

Skin Exposure: Thoroughly wash with mild soap and water if irritation develops.

Eye Exposure: Immediately flush eye with copious amounts of water and seek medical attention.

Inhalation: Inhalation exposure is not expected to occur. If symptoms occur, move to fresh air and seek medical attention.

Ingestion: Seek medical attention. Never induce vomiting to an unconscious or convulsing person.

SECTION 5: FIRE / EXPLOSION HAZARDS & FIRE-FIGHTING MEASURES

Flash Point: NE Autoignition Temperature: NE

Flammable Limits (in air by volume, %): Lower: NE Upper: NE

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK Carbon Dioxide: OK Halon: OK
Foam: OK Dry Chemical: OK Other: Any "ABC" Class

Unusual Fire and Explosion Hazards: No unusual fire or explosion hazards are expected.

Explosion Sensitivity to Mechanical Impact: Not sensitive.
Explosion Sensitivity to Static Discharge: Not sensitive.

Special Fire Fighting Procedures: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear full protective clothing and a self contained breathing apparatus. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by the DOT *Emergency Response Guidebook*, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

SECTION 6: SPILL AND LEAK PROCEDURES

Spill and Leak Response:

Clean up material and place in an appropriate disposal container. Avoid runoff into storm sewers and ditches which lead to waterways. Consult local authorities regarding notification requirements.

SECTION 7: HANDLING AND STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Storage and Handling Practices: Store at controlled room temperature 15°C to 30°C (59°F to 86°F). Store away from oxidizing agents, avoid exposure to direct light, and avoid strong bases. Wash hands before eating. Avoid contact with eyes, skin, and clothing.

Protective Practices During Maintenance of Contaminated Equipment: ND

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Ventilation and Engineering Controls: No special ventilation required under normal condition of use.

Respiratory Protection: No special requirements under normal conditions.

Eye Protection: Although the risk from eye exposure is minimal, prudence recommends the use of safety glasses.

Hand Protection: No special requirements under normal condition of use. Gloves should be worn during spill clean up.

Body Protection: No special requirements under normal conditions of use.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

SECTION 9: PHYSICAL / CHEMICAL PROPERTIES

Boiling Point:	ND	Vapor Pressure:	ND
Melting/Freezing Point:	ND	pH:	3
Water Solubility:	Soluble	Water Reactive:	No
Specific Gravity (Water =1):	ND	Evaporation Rate (Butyl acetate = 1):	ND
Appearance/Odor:	Clear red liquid with a fruity odor.		

ND = No Data

SECTION 10: STABILITY AND REACTIVITY

Stability: Stable under labeled storage conditions.

Incompatible Materials: Oxidizing agents, bases.

Hazardous Polymerization: High temperatures may liberate toxic gas.

Conditions to Avoid: Protect from light.

SECTION 11: TOXICOLOGICAL INFORMATION

Toxicity Data: Oral LD₅₀ Rat = 1600 mg/kg

Suspected Cancer Agent: This product has **NOT** been identified as a carcinogen by NTP, IARC or OSHA.

Irritancy of Product: During normal use of product no eye contact should occur.

Sensitization to the Product: Not Known.

Reproductive Information: Although VERSED Syrup has not been studied in pregnant patients an increased risk of congenital malformations associated with the use of benzodiazepine drugs (diazepam and chlordiazepoxide) have been suggested in several studies. If this drug is used during pregnancy the patient should be apprised of the potential hazard to the fetus.

Mutagenicity: ND

Embryotoxicity/Teratogenicity/Reproductive Toxicity: ND

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

SECTION 12: ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants/Animals/Aquatic Life: No information is currently available on the environmental impact of this product.

SECTION 13: WASTE DISPOSAL

Preparing Wastes for Disposal: This is a DEA class IV product. Dispose of material according to local disposal regulations or company operating procedures or DEA procedures

U.S. EPA Waste Number: None

SECTION 14: TRANSPORTATION INFORMATION

This Material is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

SECTION 15: REGULATORY INFORMATION

U.S. REGULATIONS:

U.S. SARA Reporting Requirements: 311/312 Hazard Categories: Immediate Health, 313 Reportable Ingredients: None

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Midazolam HCl syrup is a “drug” as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does NOT contain a chemical known to the State of California to cause developmental and reproductive effects.

WARNING! Midazolam HCl 2 mg/mL syrup should be administered under the supervision of a qualified physician.

SECTION 16: OTHER INFORMATION

DEFINITIONS OF ABBREVIATIONS USED:

ACGIH:	American Conference of Governmental Industry Hygienists
CAS:	Chemical Abstract Service
IARC:	International Agency for Research on Cancer
IDLH:	Immediately Dangerous to Life or Health Level
LC ₅₀ :	Medial Lethal Concentration
LD ₅₀ :	Medial Lethal Dose
MSHA:	Mine Safety and Health Administration
N/A:	Not Available
NIOSH:	National Institute for Occupational Safety and Health
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Administration
PEL:	Permissible Exposure Limit
STEL:	Short Term Exposure Limit
TLV:	Threshold Limit Value
TWA:	Time Weighted Average