



1 PRODUCT AND COMPANY INFORMATION

Distributed By:	WG Critical Care, LLC. 120 Route 17 North Suite 115 Paramus, NJ 07652 USA
Product Name:	MIDAZOLAM INJECTION
Primary Component/ Active Ingredient:	MIDAZOLAM
Chemical Name:	(1) 4 <i>H</i> -Imidazo[1,5- <i>a</i>][1,4]benzodiazepine, 8-chloro-6-(2-fluorophenyl)-1-methyl; (2) 8-Chloro-6-(<i>o</i> -fluorophenyl)-1-methyl-4 <i>H</i> -imidazo[1,5- <i>a</i>][1,4]benzodiazepine.
Molecular Formula:	C ₁₈ H ₁₃ ClFN ₃
UNII Code:	R60LOSM5BC
CAS Number:	59467-70-8
Chemical Family:	Benzodiazepine
Product Use:	Pharmaceutical
Product Type:	Prescription Drug
Container Information:	Plastic Bags
Customer Service Phone Number:	+1-888-493-0861
Emergency Phone Number:	+1-866-562-4708 (ProPharma)

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2 HAZARDS IDENTIFICATION

Classification of Substance or Mixture: Mixture Not Classified

LABEL ELEMENTS:

SIGNAL WORD: None.

HAZARD STATEMENTS: H360d – May damage the unborn child
H362 – May cause harm to breast-fed children

PRECAUTIONARY STATEMENTS: 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 hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

3 COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Weight %</u>	<u>CAS No.</u>	<u>EU EINECS ELINCS LIST</u>	<u>GHS CLASSIFICATION</u>
MIDAZOLAM	0.1	59467-70-8	261-774-5	Acute Tox. 4 (H302) Repr. 1B (H360D) Lact. (H362)
SODIUM CHLORIDE	**	7647-14-5	231-598-3	Not listed
HYDROCHLORIC ACID	**	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) acute Tox.3 (H331)
SODIUM HYDROXIDE	**	1310-73-2	215-185-5	Skin Corr. 1A (H314)
WATER FOR INJECTION	**	7732-18-5	231-791-2	Not listed

**Additional Information: Ingredients indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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4 FIRST AID MEASURES

EYE EXPOSURE:	Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
SKIN EXPOSURE:	Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.
INGESTION:	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
INHALATION:	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention.
NOTE TO PHYSICIAN:	See product package insert.

5 FIRE FIGHTING MEASURES

FLASH POINT:	Not listed
AUTO-IGNITION TEMPERATURE:	Not listed
FLAMMABLE LIMITS IN AIR:	Not listed
FLAMMABLE LIMITS:	Not listed
EXTINGUISHING MEDIA:	Dry chemical, carbon dioxide, water spray or alcohol-resistant foam
FIRE / EXPLOSION HAZARDS:	May generate flammable vapors. Fine particles (such as dust and mists) may fuel fires/explosions.
HAZARDOUS COMBUSTION PRODUCTS:	May include oxides of carbon.

NOTE TO FIRE-FIGHTERS: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

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6 ACCIDENTAL RELEASE MEASURE

Personal Precautions, Protective Equipment and Emergency Procedures: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

ENVIRONMENTAL PRECAUTIONS: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP:

MEASURES FOR CLEANING / COLLECTING: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

ADDITIONAL CONSIDERATION FOR LARGE SPILLS Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7 HANDLING AND STORAGE

GENERAL HANDLING: Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls. Avoid breathing vapor or mist.

STORAGE CONDITIONS: Store as directed by product packaging.

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8 EXPOSURE CONTROLS / PERSONAL PROTECTION

- RESPIRATORY PROTECTION:** Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)
- EYE PROTECTION:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
- VENTILATION:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
- SKIN PROTECTION:** Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
- OTHER PROTECTIVE EQUIPMENT:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

ADDITIONAL PRECAUTIONS:

<u>MATERIAL</u>	<u>ACGIH CEILING THRESHOLD LIMIT:</u>
Hydrochloric Acid	2.98mg/m ³
Sodium Hydroxide	2mg/m ³

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9 PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Solution	APPEARANCE:	Clear / Colorless to light yellow
UPPER FLAMMABILITY LIMIT:	No data available	LOWER FLAMMABILITY LIMIT:	No data available
EXPLOSIVE LIMITS:	No data available	ODOR:	Odorless
VAPOR PRESSURE:	No data available	ODOR THRESHOLD:	No data available
VAPOR DENSITY:	No data available	pH:	3.0 (2.5 – 3.5)
RELATIVE DENSITY:	No data available	MELTING POINT:	No data available
FREEZING POINT:	No data available	SOLUBILITY:	Insoluble in water. Freely soluble in ethanol, soluble in methanol
INITIAL BOILING POINT:	No data available	BOILING RANGE:	No data available
FLASH POINT:	No data available	EVAPORATION RATE:	No data available
FLAMMABILITY:	No data available	PARTITION COEFFICIENT (N-OCTANOL / WATER)	No data available
AUTO-IGNITION TEMPERATURE:	No data available	DECOMPOSITION TEMPERATURE:	No data available
VISCOSITY:	No data available	SPECIFIC GRAVITY:	No data available

10 STABILITY AND REACTIVITY

STABILITY: Stable under normal conditions of use

REACTIVITY: No data available

POSSIBILITY OF HAZARDOUS REACTIONS:

INCOMPATIBILITY : (MATERIALS TO AVOID) As a precaution keep away from strong oxidizers.

No data available

HAZARDOUS POLYMERIZATION:

HAZARDOUS DECOMPOSITION: No data available

CONDITIONS TO AVOID: Fine particles (dusts and mists) many fuel fires / explosions.

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11 TOXICOLOGICAL INFORMATION

INFORMATION ON TOXICOLOGICAL EFFECTS

GENERAL INFORMATION: The information included in this section describes the potential hazards of the individual ingredients.

SHORT TERM: May cause eye irritation (based on components). Active ingredient may be harmful if swallowed.

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

KNOWN CLINICAL EFFECTS: 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.

ACUTE TOXICITY

COMPONENT	TYPE	ROUTE	SPECIES	DOSAGE
Sodium Chloride	LD50	Oral	Rat	3000mg/kg
Sodium Chloride	LD50	Oral	Mouse	4000mg/kg
Midazolam	LD50	Oral	Rat	215mg/kg
Midazolam	LD50	Para-periosteal	Rat	75mg/kg

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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12 ECOLOGICAL INFORMATION

ENVIRONMENTAL OVERVIEW: Environmental properties have not been investigated. Any releases to the environment need to be avoided.

TOXICITY: No data available

PERSISTENCE AND DEGRADABILITY: No data available

BIO-ACCUMULATIVE POTENTIAL: No data available

MOBILITY IN SOIL: No data available

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13 DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater

14 TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15 REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

US Regulations

TSCA – No

CERCLA-No

SARA 302 – No

SARA 313 – No

OSHA Substance Specific – No

California Prop 65: Not Listed

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16 OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Reproductive toxicity-Cat.1B; H360D - May damage the unborn child

Reproductive toxicity, effects on or via lactation; H362 - May cause harm to breast-fed children

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reasons for Revision: Updated information in section 15

Revision date: 20-May, 2021

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PUROPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

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