

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Mida-AUS/DP-005

Effective Date: 08 July 2026

MIDAZOLAM SOLUTION FOR INJECTION
5 mg/5 mL, 5 mg/1 mL, 15 mg/3 mL and 50 mg/10 mL (Ampoule)
MIDAZOLAM SOLUTION FOR INJECTION
5 mg/5 mL and 50 mg/10 mL (PFS)

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: MIDAZOLAM SOLUTION FOR INJECTION 5 mg/5 mL, 5 mg/1 mL, 15 mg/3 mL and 50 mg/10 mL (Ampoule). MIDAZOLAM SOLUTION FOR INJECTION 5 mg/5 mL and 50 mg/10 mL (PFS)

Sponsor:

Accord Healthcare Pty Ltd
Level 24, 570 Bourke Street,
Melbourne, VIC, 3000,
Australia

Telephone: 1800 222 673
(Hours 8:30am – 4:30pm)

SECTION 2 – HAZARD(S) IDENTIFICATION

Classification of the Substance or Mixture:

GHS – Classification:

Carcinogenicity	:	Category 2
Reproductive toxicity (includes effects on or via lactation)	:	Category 1B

Label Elements:



Signal Word: Danger

Hazard Statements:

- H351 - Suspected of causing cancer
- H360 - May damage fertility or the unborn child
- H362 - May cause harm to breast-fed children

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Precautionary Statements:

- P201 - Obtain special instructions before use.
- 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 and while nursing.
- P264 - Wash hands thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P280 - Wear protective gloves/protective clothing/eye protection/face protection.
- P308 + P313 - If exposed or concerned: Get medical advice/attention.
- P405 - Store locked up.
- P501 - Dispose of contents/container in accordance with local, state, federal and provincial regulations.

Other Hazards: An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Active: Midazolam.

Inactive: Sodium chloride, sodium hydroxide, and water for injections.

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Midazolam	59467-70-8	261-774-5	Acute Tox. 4 (H302) Repr. 1B (H360D) Lact. (H362) Carc.2 (H351)	<= 0.5
Sodium chloride	7647-14-5	231-598-3	Not Listed	
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	
Hydrochloric acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	
Water for Injection	7732-18-5	231-791-2	Not Listed	

Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

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SECTION 4 - FIRST AID MEASURES

Description of Necessary First Aid Measures:

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known.

Medical Attention and Special Treatment: None.

SECTION 5 - FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture: Formation of toxic gases is possible during heating or fire.

Hazardous combustion products: May include oxides of carbon

Special Protective Equipment and Precautions for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

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.

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Methods and Material for Containment and Cleaning Up: 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.

SECTION 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Conditions for Safe Storage, Including any Incompatibilities: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters – Exposure Standards, Biological Monitoring:

Midazolam:

Occupational Exposure Band (OEB) : OEB 4 control exposure to the range of $1\mu\text{g}/\text{m}^3$ to $<10\mu\text{g}/\text{m}^3$

Hydrochloric acid:

ACGIH Ceiling Threshold Limit : 2 ppm
Australia PEAK : 5 ppm
7.5 mg/m³

Sodium hydroxide:

ACGIH Ceiling Threshold Limit : 2 mg/m³
Australia PEAK : 2 mg/m³

Sodium chloride

Latvia OEL - TWA : 5 mg/m³
Lithuania OEL - TWA : 5 mg/m³

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Appropriate Engineering Controls: 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.

Personal 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.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: 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.)

Skin: 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.)

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 EN140, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Solution
Colour	: Clear Colourless
Odour	: No data available.
Odour Threshold	: No data available.
Molecular Formula	: Mixture
Molecular Weight	: Mixture
Solvent Solubility	: No data available
Water Solubility	: No data available
pH	: 3.0 (2.5-3.5)
Melting/Freezing Point (°C)	: No data available
Boiling Point and boiling range (°C)	: No data available
Partition Coefficient	: No data available
Decomposition Temperature (°C)	: No data available
Evaporation Rate (Gram/s)	: No data available
Vapour Pressure (kPa)	: No data available
Vapour Density (g/ml)	: No data available
Relative Density	: No data available
Viscosity	: No data available

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Auto-ignition Temperature (Solid) (°C) : No data available
Flammability (Solids) : No data available
Flash Point (Liquid) (°C) : No data available
Upper Flammability or Explosive Limits (Liquid) (% by Vol.) : No data available
Lower Flammability or Explosive Limits (Liquid) (% by Vol.) : No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials and Possible Hazardous Reactions: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: No data available.

SECTION 11 – TOXICOLOGICAL INFORMATION

The information included in this section describes the potential hazards of the active ingredient.

Information on Toxicological Effects:

Short Term: Harmful if swallowed (based on animal data) Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. In the workplace, platinum compounds have been reported to cause allergic skin and respiratory reactions.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on testes the developing fetus. May cause effects on blood and blood forming organs.

Known Clinical Effects: Bone marrow suppression is the most serious adverse effect seen during clinical use. Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Acute Toxicity:

Midazolam:

Species:	Route	End Point	Dose
Rat	Oral	LD50	215 mg/kg
Rat	Para-periosteal	LD50	75 mg/kg

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Sodium chloride:

Species	Route	End Point	Dose
Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Sodium hydroxide:

Species	Route	End Point	Dose
Mouse	Intraperitoneal	LD50	40 mg/kg

Product Formulation

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Midazolam	= 215 mg/kg (Rat)	-	-
Sodium chloride	= 3550 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
Hydrochloric acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h
Water for injections	> 90 mL/kg (Rat)	--	-

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization:

Midazolam:

Study Type	Species	Severity
Eye Irritation	Rabbit	Minimal
Skin Irritation	Rabbit	Non-irritating

Sodium chloride:

Study Type	Species	Severity
Eye Irritation	Rabbit	Mild
Skin Irritation	Rabbit	Mild

Hydrochloric Acid:

Study Type	Severity
Skin	Severe
Eye	Severe

Irritation / Sensitization:

Midazolam:

Study Type	Species	Severity
Eye Irritation	Rabbit	Minimal
Skin Irritation	Rabbit	Non-irritating

Sodium chloride:

Study Type	Species	Severity
Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

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Sodium Hydroxide:

Study Type	Species	Severity
Skin	Rabbit	Severe
Eye	Rabbit	Severe

Hydrochloric Acid:

Study Type	Severity
Skin	Severe
Eye	Severe

Repeated Dose Toxicity:

Midazolam:

Duration	Species	Route	Dose	End Point	Target Organ
5 Week(s)	Rat	Intravenous	1 mg/kg/day	NOAEL	Central nervous system
5 Week(s)	Dog	Intravenous	1 mg/kg/day	NOAEL	Central nervous system

Reproduction & Development Toxicity:

Midazolam:

Study Type	Species	Route	Dose	End Point	Effect (s)
Reproductive & Fertility	Rat	Oral	16 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rat	Oral	120 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Mouse	Oral	120 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rabbit	Oral	100 mg/kg/day	NOAEL	Not Teratogenic

Genetic Toxicity:

Midazolam:

Study Type	Cell Type/Organism	Severity
Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
Micronucleus	Mouse	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vitro</i> Micronucleus	Hamster	Negative

Hydrochloric acid:

Study Type	Cell Type/Organism	Severity
Bacterial Mutagenicity (Ames)	<i>Salmonella</i>	Negative
<i>In Vivo</i> Micronucleus	Rat	Negative

Carcinogenicity:

Midazolam:

Duration	Species	Route	Dose	End Point	Effect (s)
2 Year(s)	Male Rat	Oral, in feed	9 mg/kg/day	NOAEL	Benign, Thyroid, Tumors
2 Year(s)	Female Mouse	Oral, in feed	9 mg/kg/day	NOAEL	Liver, Tumors

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Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below

Hydrochloric Acid

IARC: Group 3 (Not Classifiable)

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available.

Bacterial inhibition: No data available.

Chronic aquatic toxicity: No data available.

Persistence and Degradability: No data available.

Bio-accumulative Potential: No data available.

Mobility in Soil: No data available.

Results of PBT and vPvB assessment:

Chemical name	PBT and vPvB assessment
Sodium chloride	The substance is not PBT / vPvB PBT assessment does not apply
Sodium hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
Hydrochloric acid	The substance is not PBT / vPvB PBT assessment does not apply

Endocrine disrupting properties: No data available.

Other Adverse Effects: No data available.

SECTION 13 – DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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

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available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

SECTION 14 – TRANSPORTATION INFORMATION

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

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

UN number: Not applicable

UN proper shipping name: Not applicable

Transport hazard class(es): Not applicable

Packing group: Not applicable

Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

SECTION 15 - REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Midazolam:

CERCLA/SARA Section 313 de minimus %	: Not Listed
California Proposition 65	: developmental toxicity 10/1/1992
U.S. - DEA (Drug Enforcement Administration)	: Schedule IV Controlled Substance
Standard for the Uniform Scheduling for Drugs and Poisons	Schedule 4
EINECS	: 261-774-5

Sodium hydroxide:

CERCLA/SARA Section 313 de minimus %	: Not Listed
CERCLA/SARA Hazardous substances and their reportable quantities	: 1000 lb
California Proposition 65	: Not Listed
Inventory - United States TSCA - Sect. 8(b)	: Present
Australia (AICS)	: Present
Standard for the Uniform Scheduling for Drugs and Poisons	: Schedule 5 Schedule 6
EINECS	: 215-185-5

Sodium chloride:

CERCLA/SARA Section 313 de minimus %	: Not Listed
California Proposition 65	: Not Listed
Inventory - United States TSCA - Sect. 8(b)	: Present
Australia (AICS)	: Present

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EINECS : 231-595-7

Hydrochloric acid:

CERCLA/SARA Section 313 de minimus % : 1.0%
CERCLA/SARA Hazardous substances and their reportable quantities : 5000 lb
2270 kg
CERCLA/SARA – Section 302 Extremely hazardous TPQs : 500 lb
California Proposition 65 : Not Listed
Inventory - United States TSCA - Sect. 8(b) : Present
Australia (AICS) : Present
Standard for the Uniform Scheduling for Drugs and Poisons : Schedule 5
Schedule 6
EINECS : 231-595-7

Water for Injections:

CERCLA/SARA Section 313 de minimus % : Not Listed
California Proposition 65 : Not Listed
Inventory - United States TSCA - Sect. 8(b) : Present
Australia (AICS) : Present
EINECS : 231-791-2

SECTION 16 - OTHER INFORMATION

Abbreviations:

ACGIH : American Conference of Governmental Industrial Hygienists
AICS : Australian Inventory of Chemical Substances
AIHA : American Industrial Hygiene Association
ANSI : American National Standards Institute
CAS : Number Chemical Abstract Service Registry Number
CERCLA : Comprehensive Environmental Response Compensation and Liability Act
CHAN : Chemical Hazard Alert Notice
CHEMTREC : Chemical Transportation Emergency Center
DOT : Department of Transportation
DSL : Domestic Substances List
ECHA : European Chemicals Agency
EINECS : European Inventory of Existing Commercial Chemical Substances
ELINCS : European List of Notified Chemical Substances
EPA : Environmental Protection Agency
GHS : Globally Harmonized System of Classification and Labelling of Chemicals
HEPA : High Efficiency Particulate Air (Filter)
HMIS : Hazardous Materials Identification System
IARC : International Agency for Research on Cancer
ICAO/IATA : International Civil Aviation Organization/International Air Transport
IMO : International Maritime Organization
KOW : Octanol/Water Partition Coefficient
LEL : Lower Explosive Limit

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MSDS	: Material Safety Data Sheet
MSHA	: Mine Safety and Health Administration
NA	: Not Applicable, except in Section 14 where NA = North America
NE	: Not Established
NADA	: New Animal Drug Application
NAIF	: No Applicable Information Found
NCI	: National Cancer Institute
NDSL	: Non-Domestic Substances List
NFPA	: National Fire Protection Association
NIOSH	: National Institute for Occupational Safety and Health
NPDES	: National Pollutant Discharge Elimination System
NOS	: Not Otherwise Specified
NTP	: National Toxicology Program
OSHA	: Occupational Safety and Health Administration
OEL	: Occupational Exposure Limit
PEL	: Permissible Exposure Limit (OSHA)
RCRA	: Resource Conservation and Recovery Act
RQ	: Reportable Quantity
RTECS	: Registry of Toxic Effects of Chemical Substances
SARA	: Superfund Amendments and Reauthorization Act
SDS	: Safety Data Sheet
STEL	: Short Term Exposure Limit
TLV	: Threshold Limit Value (ACGIH)
TPQ	: Threshold Planning Quantity
TSCA	: Toxic Substances Control Act
TWA	: Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	: Upper Explosive Limit
UN	: United Nations
USP	: United States Pharmacopeia
WEEL	: Workplace Environmental Exposure Level (AIHA)
WHMIS	: Workplace Hazardous Materials Information System

Data Sources: Information from published literature.

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall INTAS be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if INTAS has been advised of the possibility of such damages.