

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Mida-AUS/DP-003

Effective Date: 07th April 2020

MIDAZOLAM INJECTION, 5 MG/5 ML, 5 MG/1 ML, 15 MG/3 ML AND 50 MG/ 10 ML

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Midazolam Injection, 5 mg/5 mL, 5 mg/1 mL, 15 mg/3 mL and 50 mg/10 mL

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against	
Intended Use:	Pharmaceutical product used as antianxiety agent
Details of the Supplier of the Safety Data Sheet	
Manufacturer:	Sponsor:
Intas Pharmaceuticals Ltd. Plot No. 457, 458 Village-Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad-382 210, Gujarat, India	Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia

SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

Hazardous

Active 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)	</= 0.5

Inactive Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
hydrochloric acid and	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:

* Proprietary
Ingredient(s) 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.

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

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SECTION 3 - HAZARDS IDENTIFICATION

Classification of the Substance or Mixture:

GHS – Classification

Reproductive Toxicity: Category 1B Effects on or via lactation

Label Elements:

Signal Word: Danger

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.



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 4 - FIRST AID MEASURES

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Description of First Aid Measures:

- Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.
- Skin Contact:** 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.

Most Important Symptoms and Effects, Both Acute and Delayed:

- Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 3 – Hazards Identification and/or Section 11 - Toxicological Information.
- Medical Conditions:** None known
- Aggravated by Exposure:**

Indication of the Immediate Medical Attention and Special Treatment Needed:

- Notes to Physician:** None

SECTION 5 - FIRE FIGHTING MEASURES

- Extinguishing Media:** Dry chemical, carbon dioxide, water spray or alcohol-resistant foam.

Special Hazards Arising from the Substance or Mixture:

- Hazardous Combustion Products:** May include oxides of carbon.
- Fire / Explosion Hazards:** May generate flammable vapors. Fine particles (such as dust and mists) may fuel fires/explosions
- Advice for Fire-Fighters:** During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

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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.

SECTION 7 - HANDLING AND STORAGE

Precautions for Safe 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.

Conditions for Safe Storage, Including any Incompatibilities:

Storage Conditions: Store as directed by product packaging

Specific end use(s): Pharmaceutical drug product

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters:

Midazolam

Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of 1ug/m³ to <10ug/m³)

Refer to available public information for specific member state Occupational Exposure Limits.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but

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inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Sodium chloride

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

Hydrochloric Acid

ACGIH Ceiling Threshold Limit : 2 ppm
Australia PEAK : 5 ppm
7.5 mg/m³
Austria OEL – MAKs : 5 ppm
8 mg/m³
Belgium OEL - TWA : 5 ppm
8 mg/m³
Bulgaria OEL - TWA : 5 ppm
8.0 mg/m³
Cyprus OEL - TWA : 5 ppm
8 mg/m³
Czech Republic OEL - TWA : 8 mg/m³
Estonia OEL - TWA : 5 ppm
8 mg/m³
Germany - TRGS 900 - TWAs : 2 ppm
3 mg/m³
Germany (DFG) - MAK : 2 ppm
3.0 mg/m³
Greece OEL - TWA : 5 ppm
7 mg/m³
Hungary OEL - TWA : 8 mg/m³
Ireland OEL - TWAs : 5 ppm
8 mg/m³
Italy OEL - TWA : 5 ppm
8 mg/m³
Japan - OELs - Ceilings : 2 ppm
3.0 mg/m³
Latvia OEL – TWA : 5 ppm
8 mg/m³
Lithuania OEL - TWA : 5 ppm
8 mg/m³
Luxembourg OEL - TWA : 5 ppm
8 mg/m³
Malta OEL - TWA : 5 ppm
8 mg/m³
Netherlands OEL - TWA : 8 mg/m³
Poland OEL - TWA : 5 mg/m³
Portugal OEL - TWA : 5 ppm

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Romania OEL - TWA	: 8 mg/m ³ 5 ppm
Slovakia OEL - TWA	: 8 mg/m ³ 5 ppm
Slovenia OEL - TWA	: 8.0 mg/m ³ 5 ppm
Spain OEL – TWA	: 8 mg/m ³ 5 ppm
Switzerland OEL –TWAs	: 7.6 mg/m ³ 2 ppm
Vietnam OEL - TWAs	: 3.0 mg/m ³ 5 mg/m ³

Sodium hydroxide

ACGIH Ceiling Threshold Limit	: 2 mg/m ³
Australia PEAK	: 2 mg/m ³
Austria OEL – MAKs	: 2 mg/m ³
Bulgaria OEL – TWA	: 2.0 mg/m ³
Czech Republic OEL – TWA	: 1 mg/m ³
Estonia OEL – TWA	: 1 mg/m ³
France OEL – TWA	: 2 mg/m ³
Greece OEL – TWA	: 2 mg/m ³
Hungary OEL – TWA	: 2 mg/m ³
Japan - OELs – Ceilings	: 2 mg/m ³
Latvia OEL – TWA	: 0.5 mg/m ³
OSHA - Final PELs - TWAs	: 2 mg/m ³
Poland OEL – TWA	: 0.5 mg/m ³
Slovakia OEL – TWA	: 2 mg/m ³
Slovenia OEL – TWA	: 2 mg/m ³
Sweden OEL - TWAs	: 1 mg/m ³

Exposure Controls

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

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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 EN136, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solution
Color:	Clear Colorless
Odor:	No data available.
Odor 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 (°C):	No data available
Partition Coefficient: (Method, pH, Endpoint, Value)	
Water, purified:	No data available
Sodium chloride:	No data available
Midazolam:	No data available
Hydrochloric Acid:	No data available
SODIUM HYDROXIDE:	No data available
Decomposition Temperature (°C):	No data available
Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available
Flammability:	
Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available

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Lower 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.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

SECTION 11 - TOXICOLOGY 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:

Midazolam:

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

Sodium chloride:

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

Irritation / Sensitization:

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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

Hydrochloric Acid:

Study Type	Severity
Skin	Severe
Eye	Severe

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	120 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

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

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

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Hydrochloric Acid

IARC: Group 3 (Not Classifiable)

SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

Environmental Overview:	Environmental properties have not been investigated. Releases to the environment should be avoided
Toxicity:	No data available
Persistence and Degradability:	No data available
Bio-accumulative Potential:	No data available
Mobility in Soil:	No data available

SECTION 13 - DISPOSAL INFORMATION

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

SECTION 15 - REGULATORY INFORMATION

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

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CERCLA/SARA 313 Emission reporting : Not Listed

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California Proposition 65 : Not Listed
U.S. Drug Enforcement Administration Standard for the Uniform Scheduling for Drugs and Poisons: : Schedule IV Controlled Substance
: Schedule 4
EU EINECS/ELINCS List : 261-774-5

Sodium chloride:

CERCLA/SARA 313 Emission reporting : Not Listed
California Proposition 65 : Not Listed
Inventory - United States TSCA - Sect. 8(b) : Present
Australia (AICS): : Present
EU EINECS/ELINCS List : 231-598-3

Hydrochloric Acid:

CERCLA/SARA 313 Emission reporting : 1.0 %
CERCLA/SARA Hazardous Substances and their Reportable Quantities: : 5000 lb
: 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous TPQs : 500 lb
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs : 5000 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
EU EINECS/ELINCS List : 231-595-7

Sodium hydroxide:

CERCLA/SARA 313 Emission reporting : Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities : 1000 lb
: 454 kg
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
EU EINECS/ELINCS List : 215-185-5

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SECTION 16 - OTHER DATA

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.

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