3005 avenue José-Maria Rosell
St-Hyacinthe, QC J2S 0J9
Canada

https://sterinova.com/

MSDS MIDAZOLAM INJECTION

Status: Approved & Effective
Effective Date: N/A
Control Number: N/A
Version: 1.0

DOCUMENT INFORMATION TABLE

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Originator (Author)	nancy.wanner@sterinova.com (Nancy Wanner)
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RELATED ITEMS

N/A

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APPROVAL TABLE

Status[1]	Selected for Approval username (Full Name), *Title*	Approved By username (Full Name)	Meaning	Approval Date
APP	nancy.wanner@sterinova.com (Nancy Wanner), *Compliance Associate*	nancy.wanner@sterinova.com (Nancy Wanner)	Originator (Author)	2025-01-17 15:32:32 UTC-05:00
APP	daniel.abran@sterinova.com (Daniel Abran), *V.P. Quality and Regulatory Affairs*	daniel.abran@sterinova.com (Daniel Abran)	Approver	2025-01-18 10:00:30 UTC-05:00

[1] Legend:
NS: Not Started
AWA: Awaiting Approval
APP: Approved
REJ: Rejected
STO: Stopped

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SAFETY DATA SHEET

Product Name: **Midazolam Injection, USP**

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address	**Sterinova Inc.** 3005 ave José-Maria-Rosell St-Hyacinthe, J2S 0J9, Quebec Canada
Emergency Telephone **Med Info** **Courriel**	**Sterinova Inc.** **+1-844-329-2939** **medinfo@sterinova.com**
Product Name	**Midazolam Injection, USP**
Synonyms	**8-Chloro-6-(2-Fluorophynil) -1-methyl-4H-imidazo(1,5-a)(1,4)benzodiazepine hydrochloride**

2. HAZARD(S) 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



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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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredients	CAS Number	GHS Classification	%
Midazolam USP	59467-70-8	Acute Tox. 4 (H302) Repr. 1B (H360D) Lact. (H362)	0.1
Concentrated Hydrochloric Acid	7647-01-0	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	*
Sodium Chloride	7647-14-5	-	*
0.1 N NaOH	1310-73-2	Skin Corr. 1A (H314)	*

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

4. FIRST AID MEASURES

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 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

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Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

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 fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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.

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

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.

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Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Hydrochloric Acid

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

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

Midazolam

Pfizer Occupational Exposure Band (OEB):	OEB 4 (control exposure to the range of 1ug/m^3 to <10ug/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.

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

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

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Viscosity: No data available

Flammablity:

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
Lower Explosive Limits (Liquid) (% by Vol.):	No data available

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

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: (Species, Route, End Point, Dose)

Sodium chloride

Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Midazolam

Rat	Oral	LD50	215 mg/kg
Rat	Para-periosteal	LD50	75 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride

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Eye irritation	Rabbit	Moderate
Skin irritation	Rabbit	Mild

Midazolam

Eye irritation	Rabbit	Minimal
Skin irritation	Rabbit	Non-irritating

Hydrochloric Acid

Skin irritation	Severe
Eye irritation	Severe

Reproductive & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Midazolam

Reproductive & Fertility	Rat	Oral	16 mg/kg/day	NOAEL	No effect 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: (Study Type, Cell Type/Organism, Result)

Midazolam

Bacterial Mutagenicity (Ames)	*Salmonella*	Negative
Micronucleus	Mouse	Negative
In Vitro Chromosome Aberration	Human Lymphocytes	Negative
In Vitro Micronucleus	Hamster	Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Midazolam

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

Hydrochloric Acid

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL 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

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Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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 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

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

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

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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

Midazolam

CERCLA/SARA 313 Emission reporting	Not listed
California Proposition 65	Not listed
U.S. Drug Enforcement Administration:	Schedule IV Controlled Substance Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	261-774-5

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:	New data sheet.
Revision date:	2025-01-14
Prepared by:	Product Stewardship Hazard Communication Sterinova

Sterinova Inc. believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet