

**MATERIAL SAFETY DATA SHEET****NOVARTIS PHARMACEUTICALS CORPORATION**One Health Plaza
East Hanover, NJ 07936**24-Hour Emergency Telephone Number:** 1-862-778-7000**Customer Interaction Center (MSDS requests):** 1-888-669-6682**For Technical Information:** 1-862-778-3680 (9:00 AM – 5:00 PM E.S.T.)**SECTION 1. PRODUCT IDENTIFICATION**

PRODUCT NAME: **Methergine ®Injection, USP**
SYNONYMS: Ergot alkaloid
THERAPEUTIC CATEGORY: Prevention and control of postpartum hemorrhage.
GENERIC NAME: Methylergonovine maleate, USP
CHEMICAL NAME: Ergoline-8-carboxamide,9,10-didehydro-N-[1-(hydroxymethyl)propyl]-6-methyl-,[8β(S)]-,(Z)-2-butenedioate (1:1) (salt)
CHEMICAL FORMULA: C₂₀H₂₅N₃O₂•C₄H₄O₄
MOLECULAR WEIGHT: 455.51

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

<u>COMPOSITION</u>	<u>CAS#</u>	<u>CONCENTRATION</u>
Methylergometrine	57432-61-8	0.2 mg/ml

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

FINISHED PHARMACEUTICAL PRODUCT
REFER TO PHYSICIANS' DESK REFERENCE

PRIMARY ROUTE(S) OF ENTRY: Injection

EFFECTS OF OVEREXPOSURE: Finished pharmaceutical product. Potential for exposure is reduced in this form.

Skin: No hazard is expected from normal clinical use.

Eye: No hazard is expected from normal clinical use.

Inhalation: No hazard is expected from normal clinical use.

Ingestion: No hazard is expected from normal clinical use.

THERAPEUTIC SIDE EFFECTS: Hypertension, seizures, headaches, hypotension, nausea, and vomiting.

TARGET ORGAN EFFECTS: No information at this time.

REPRODUCTIVE HAZARDS: No information at this time.

CARCINOGENICITY: No information at this time.

MUTAGENICITY: No information at this time.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Individuals with hypertension, Pregnancy, Toximia.

SECTION 4. EMERGENCY AND FIRST AID MEASURES

Skin Contact: Wash contaminated area with soap and water.

Eye Contact: Flush with running water for 15 minutes holding eyelids open.

Inhalation: No specific treatment is necessary since this product is not likely to be hazardous by inhalation.

Ingestion: Get medical attention immediately, induce vomiting if victim is conscious.

SECTION 5. FIRE FIGHTING MEASURES

Flash Point: Not applicable **Method Used:** Not applicable

Flammable Limits (% in air)

Lower: not applicable Upper: not applicable

Autoignition Temperature: Not available

Extinguishing Media: Use media suitable for fire in surrounding area.

Special Fire Fighting Procedures and Precautions: Evacuate area and fight fire from safe distance.

Fire and Explosion Hazards: Not available

Fire-Fighting Equipment: Wear full protective clothing and positive pressure self-contained breathing apparatus.

Decomposition Products: Thermal decomposition may result in the emission of carbon monoxide, carbon dioxide and nitrogen oxides.

NFPA Ratings: Health = 0 Flammability = 0 Reactivity = 0 Special Hazard = None

Hazard Rating Scales: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe U = Unknown

SECTION 6. ACCIDENTAL RELEASE MEASURES

Steps to be taken if Material is Released or Spilled: Using appropriate protective equipment, sweep up and containerize spilled material. Avoid contamination of sewers and waterways.

SECTION 7. HANDLING AND STORAGE

Storage Temperature: Store below 77^oF (30^oC) away from light.
Shelf Life: Not available
Special Sensitivity: Protect from light and freezing.
Handling and Storage Precautions: Administer only if solution is clear and colorless. Avoid direct sunlight, sparks and open flame.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Eye Protection: Not required under normal conditions of therapeutic administration and use.
Skin Protection: Not required under normal conditions of therapeutic administration and use.
Respiratory Protection: Not required under normal conditions of therapeutic administration and use.
Ventilation Requirements: Not required under normal conditions of therapeutic administration and use.
Additional Measures: None

Exposure Limits (Definition of terms):

ACGIH: American Conference of Governmental Industrial Hygienists
Ceiling: Ceiling Value
DTEL: Derived Target Exposure Limit
MAK: Federal Republic of Germany Maximum Concentration Values in the Workplace
NIOSH: National Institute for Occupational Safety and Health
OSHA: Occupational Safety and Health Administration [USA]
PEL: Permissible Exposure Limit
NPIEL: Novartis Pharma Internal Exposure Limit
ppm: parts per million
REL: Recommended Exposure Limit
Skin (notation): Absorbed through skin
STEL: Short Term Exposure Limit
TLV: Threshold Limit Values
TWA: Time-Weighted Average

Component
Methylergometrine

Exposure Limit
NPIEL = 0.005 mg/m³

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Liquid	Odor Threshold:	Not available
Color:	Clear, colorless	Odor Characteristics:	Not available
pH:	Not available	Vapor Pressure (mm Hg):	Not available
Boiling Point:	Not available	Vapor Density:	Not available
Melting/Freezing Pt.:	Not available	Specific Gravity:	Not available
Soluble In:	Water	% Volatile by Wt:	Not available
		Viscosity:	Not available

SECTION 10. STABILITY AND REACTIVITY

Stable (yes/no):	Yes
Hazardous Polymerization:	Will not occur.
Conditions and Materials to Avoid:	Protect from light and temperatures exceeding 86°F (30°C). Protect from freezing.
Incompatibility:	None known
Hazardous Decomposition Products:	Thermal decomposition may result in the emission of carbon monoxide, carbon dioxide, and nitrogen oxides.

SECTION 11. TOXICOLOGICAL INFORMATION

Eye Irritation:	No data available.
Skin Irritation/Sensitization:	No data available.
Oral Toxicity:	LD50 (mouse) 187 mg/kg LD50 (rat) 93 mg/kg LD50 (rabbit) 4.5 mg/kg
Dermal Toxicity:	No data available.
Parenteral Toxicity:	No data available.
Inhalation Toxicity:	No data available.
Subchronic:	No data available.
Chronic/Carcinogenicity:	Carcinogenicity studies have not been performed
Mutagenicity:	Mutagenicity studies have not been performed.
Reproductive Effects:	FDA Use in Pregnancy Category C: Reproductive studies have not been performed. The use of Methergine is contraindicated during pregnancy because of its uterotonic effects.

SECTION 12. ECOLOGICAL INFORMATION

No data available.

SECTION 13. DISPOSAL CONSIDERATIONS

Waste Disposal Method: All wastes must be disposed of in accordance with local, state and federal laws and regulations. (Contact local or state environmental agency for specific rules).

EPA Hazardous Waste Number: None

SECTION 14. TRANSPORTATION INFORMATION

Ground Regulations:

Proper Shipping Description: Drugs, N.O.I. NMFC Item 60000
DOT Proper Shipping Name: Not Applicable
DOT Hazard Class: Not Applicable
DOT Identification Number: Not Applicable
Packing Group: Not Applicable
Hazard Label: Not Applicable
Special Requirements: Not Applicable
Exceptions: Not Applicable
Non-Bulk Requirements: Not Applicable
Bulk Requirements: Not Applicable
Reportable Quantity (lbs.): Not Applicable
Stowage: Not Applicable
Other Requirements: Not Applicable

Air Regulations:

Proper Shipping Description: Drugs, N.O.I. NMFC Item 60000
IATA Proper Shipping Name: Not Applicable
IATA Hazard Class: Not Applicable
IATA Identification Number: Not Applicable
Packing Group: Not Applicable
Hazard Label: Not Applicable
Special Requirements: Not Applicable
Max. wgt/pkg - Passgr. Aircraft: Not Applicable
Max. wgt/pkg - Cargo Only Air: Not Applicable

SECTION 15. REGULATORY INFORMATION

OSHA (Occupational Safety & Health Administration): This Material Safety Data Sheet contains the information required by the Federal OSHA Hazard Communication Standard (29 CFR 1910.1200).

OSHA PSM (Process Safety Management): Not listed (29 CFR 1910.119, Appendix A)

NJ TCPA (Toxic Catastrophe Prevention Act): This product contains NONE of the substances subject to the reporting requirements of Section N.J.A.C. 7:31 of this act.

TSCA (Toxic Substance Control Act): Not applicable

CERCLA (Comprehensive Response Compensation & Liability Act): Not listed

SARA Title III (Superfund Amendments & Reauthorization Act):

Section 302 Extremely Hazardous Substances:	Not listed
Section 311/312 Hazard Categories:	None
Section 313 Reportable Ingredients:	Not listed

RCRA (Resource Conservation & Recovery Act): Not listed

Other State Regulatory Information:

New Jersey: NJ RTK Threshold Planning Quantity = 10,000 lbs.

Other USA Regulations: None

California Proposition 65: The following statement is made in order to comply with the California Safe Drinking Water and Toxic Enforcement Act of 1986. *This product does not contain any ingredient known to the State of California to cause cancer or reproductive toxicity.*

Canada: WHMIS Ingredient Disclosure List
Not listed

EEC Classification (European Economic Community): **Warning Symbol:** not available.
Risk Phrases: not available.
Safety Phrases: not available.

SECTION 16. OTHER INFORMATION

Reason for Issue: Revision #2 – Changes to Company address; changes to Company and Emergency telephone numbers; Section 2 – revised name of active component; section 8 – addition of NPIEL.

Supersedes Date:	9 Feb 01	Date:	22 Nov 02
Written By:	C. Perino	Date:	22 Nov 02
Approved By:	J. Affuso		

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