



## 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: C<sub>20</sub>H<sub>25</sub>N<sub>3</sub>O<sub>2</sub>•C<sub>4</sub>H<sub>4</sub>O<sub>4</sub>  
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

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**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<sup>0</sup>F (30<sup>0</sup>C) 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

<u>Component</u>	<u>Exposure Limit</u>
Methylergometrine	NPIEL = 0.005 mg/m <sup>3</sup>

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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

## SECTION 10. STABILITY AND REACTIVITY

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

## SECTION 11. TOXICOLOGICAL INFORMATION

<b>Eye Irritation:</b>	No data available.
<b>Skin Irritation/Sensitization:</b>	No data available.
<b>Oral Toxicity:</b>	LD50 (mouse) 187 mg/kg LD50 (rat) 93 mg/kg LD50 (rabbit) 4.5 mg/kg
<b>Dermal Toxicity:</b>	No data available.
<b>Parenteral Toxicity:</b>	No data available.
<b>Inhalation Toxicity:</b>	No data available.
<b>Subchronic:</b>	No data available.
<b>Chronic/Carcinogenicity:</b>	Carcinogenicity studies have not been performed
<b>Mutagenicity:</b>	Mutagenicity studies have not been performed.
<b>Reproductive Effects:</b>	<b>FDA Use in Pregnancy Category C:</b> 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)

<b>NJ TCPA (Toxic Catastrophe Prevention Act):</b>	This product contains NONE of the substances subject to the reporting requirements of Section N.J.A.C. 7:31 of this act.	
<b>TSCA (Toxic Substance Control Act):</b>	Not applicable	
<b>CERCLA (Comprehensive Response Compensation &amp; Liability Act):</b>		Not listed
<b>SARA Title III (Superfund Amendments &amp; Reauthorization Act):</b>		
Section 302 Extremely Hazardous Substances:	Not listed	
Section 311/312 Hazard Categories:	None	
Section 313 Reportable Ingredients:	Not listed	
<b>RCRA (Resource Conservation &amp; Recovery Act):</b>	Not listed	
<b>Other State Regulatory Information:</b>		
<b>New Jersey:</b>	NJ RTK Threshold Planning Quantity = 10,000 lbs.	
<b>Other USA Regulations:</b>	None	
<b>California Proposition 65:</b>	<p>The following statement is made in order to comply with the California Safe Drinking Water and Toxic Enforcement Act of 1986. <i>This product does not contain any ingredient known to the State of California to cause cancer or reproductive toxicity.</i></p>	
<b>Canada:</b>	<u>WHMIS Ingredient Disclosure List</u> Not listed	
<b>EEC Classification (European Economic Community):</b>	<b>Warning Symbol:</b> not available. <b>Risk Phrases:</b> not available. <b>Safety Phrases:</b> 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.

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

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