

## SAFETY DATA SHEET

1. Identification

**Product Identifier:** Methylergonovine Maleate Injection, USP

**Synonyms:** Methylergometrine maleate

**National Drug Code (NDC):** 17478-501-01

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

**Hazard Overview:** The active ingredient, Methylergonovine Maleate, has been identified as toxic, mutagenic and having a possible risk of impaired fertility, affecting the female reproductive system.

**Physical Hazards:** Not classifiable.  
**Health Hazards:** Not classifiable.  
**Symbol(s):** None.  
**Signal Word:** None.  
**Hazard Statement(s):** None.  
**Precautionary Statement(s):** None.  
**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Methylergonovine Maleate	57432-61-8	Methylergometrine maleate	$C_{20}H_{25}N_3O_2 \cdot C_4H_4O_4$	455.51	0.02%

\*The formula also contains Maleic Acid, 0.10 mg; Sodium Chloride, 7.0 mg; and Water for Injection.

**4. First Aid Measures**

<b>Ingestion:</b>	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
<b>Eye Contact:</b>	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Contact:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Exposure may cause irritation, nausea, dizziness and headache. Overexposure to methylergonovine maleate by pregnant women may cause abortion or fetal harm. Potential for exposure is reduced in this form as a finished pharmaceutical product under normal clinical conditions.
<b>Medical Conditions Aggravated by Exposure:</b>	Individuals with hypertension, pregnancy, toxemia, or sensitivity to methylergonovine maleate. Persons sensitive to methylergonovine maleate may experience an allergic reaction. Exposure is not recommended for persons who are pregnant due to the potential oxytocic and uterotonic effects of the active ingredient.
<b>Notes to Physician:</b>	Treat supportively and symptomatically. Additional information is available in the package insert.

5. **Firefighting Measures**

**Suitable Extinguishing Media:** Multi-purpose, water mist or foam, as appropriate to surrounding media.

**Unsuitable Extinguishing Media:** Not determined.

**Specific Hazards Arising from the Chemical:**

**Hazardous Combustion Products:** Not determined.

**Other Specific Hazards:** Not determined.

**Special Protective Equipment  
Precautions for Firefighters:** Evacuate personnel. Wear self-contained breathing apparatus and full and protective gear.

6. **Accidental Release Measures**

**Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Wear appropriate personal protective equipment and avoid direct contact with material. Contain the spill to prevent additional exposure by personnel and contact with drains, sewers and streams. Absorb with a suitable agent. Dispose of all contaminated material in appropriate containers in accordance with local, state and federal regulations.

**Environmental Precautions:** Prevent further leakage or spillage if safe to do so. Prevent entry into waterways, sewers, basements or confined areas. Contact local authorities if release occurs into drains, sewers, streams or other public areas.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

7. **Handling and Storage**

**Precautions for Safe Handling:** Handle with substance only in original and closed package. Avoid dust formation. Avoid contact with skin and eyes. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,  
Including Any Incompatibilities:** Store according to label and/or product insert information. Keep containers tightly closed in a dry, cool and well-ventilated place. Store under refrigeration at temperature from +2°C to +8°C (36° to 46°F). Protect from prolonged exposure to light and avoid excessive heat.

**Specific End Use:** Pharmaceuticals.

8. **Exposure Controls/Personal Protection**

**Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits
Methylergonovine Maleate	0.005 mg/m <sup>3</sup> TWA

- Engineering Controls:** Engineering controls should be used as the primary means to control exposures.
- Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
- Eyes Protection:** Not required for the normal use of this product. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
- Hand Protection:** Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
- Skin Protection:** Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. **Physical and Chemical Properties**

- Physical State/Color:** Clear, colorless liquid.
- Odor:** Odorless.
- Odor Threshold:** No data available.
- pH:** 2.7 – 3.5.
- Melting Point:** No data available.
- Freezing Point:** No data available.
- Boiling Point:** Approximate to water.
- Flash Point:** No data available.
- Evaporation Rate:** Approximate to water.
- Flammability (solid, gas):** No data available.
- Flammability Limit - Lower:** No data available.
- Flammability Limit - Upper:** No data available.
- Vapor Pressure:** Approximate to water.
- Vapor Density:** Approximate to water.
- Relative Density:** Approximate to water.

**Solubility(ies):** Soluble in water.  
**Partition Coefficient (n-octanol/water):** No data available.  
**Auto-Ignition Temperature:** No data available.  
**Decomposition Temperature:** No data available.  
**Viscosity:** Approximate to water.

**10. Stability and Reactivity**

**Reactivity:** No data available.  
**Chemical Stability:** Stable under recommended storage conditions.  
**Possibility of Hazardous Reactions:** No data available.  
**Conditions to Avoid (e.g., static discharge, shock, or vibration):** High temperature, light, freezing.  
**Incompatible Materials:** Macrolide antibiotics and protease inhibitors.  
**Hazardous Decomposition Products:** Under fire condition emits toxic fumes and gases – carbon monoxide, carbon dioxide and nitrous oxides.  
**Hazardous Polymerization:** Does not occur.

**11. Toxicological Information**

**Information on the Likely Routes of Exposure:**

**Inhalation:** Exposure due to inhalation is unlikely.  
**Ingestion:** Exposure due to ingestion is unlikely.  
**Skin Contact:** Absorption may occur through the skin.  
**Eye Contact:** Absorption may occur through the eyes.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

**Acute Toxicity:**

Compound	Species	Route	Type	Dose
Methylergonovine Maleate	Rat	Oral	LD <sub>50</sub>	93 to 105 mg/kg
Methylergonovine Maleate	Mouse	Oral	LD <sub>50</sub>	187 mg/kg
Methylergonovine Maleate	Rat	Intravenous	LD <sub>50</sub>	23 mg/kg
Methylergonovine Maleate	Mouse	Intravenous	LD <sub>50</sub>	85 mg/kg
Methylergonovine Maleate	Rabbit	Intravenous	LD <sub>50</sub>	2.6 mg/kg
Methylergonovine Maleate	Human	Intravenous	LD <sub>50</sub>	200-300 mg/kg (estimated)

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<b>Acute Toxicity – Dermal:</b>	No data available.
<b>Acute Toxicity – Inhalation:</b>	No data available.
<b>Corrosivity:</b>	No data available.
<b>Dermal Irritation:</b>	Irritant.
<b>Eye Irritation:</b>	Irritant.
<b>Sensitization:</b>	Can influence allergic reactions in sensitive individuals.
<b>Toxicokinetics/Metabolism:</b>	No data available.
<b>Target Organ Effects:</b>	Female reproductive system.
<b>Reproductive Effects:</b>	<p>The use of Methylergonovine Maleate Injection, USP is contraindicated during pregnancy because of its oxytocic and uterotonic effects. The active ingredient has been identified as a reproductive hazard upon chronic exposure, resulting in abortion or fetal harm, effects on the female reproductive system and developmental abnormalities of the cardiovascular (circulatory) system.</p> <p>Therapeutic side effects include seizures, hypertension, headaches, nausea, and vomiting. Symptoms of acute overdose may include: nausea, vomiting, dizziness, headache, abdominal pain, tingling of the extremities, rise in blood pressure, in several cases followed by hypertension, respiratory depression, hypothermia, convulsions, and coma.</p>
<b>Carcinogenicity:</b>	Long term studies in animals show no carcinogenic potential.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
<b>Mutagenicity:</b>	No data available.
<b>Aspiration Hazard:</b>	Based on available data, the classification criteria are not met.

### 12. Ecological Information

#### Ecotoxicity

<b>Aquatic:</b>	No data available.
<b>Terrestrial:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

**13. Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

**14. Transport Information**

<b>UN Number:</b>	Not applicable.
<b>UN Proper Shipping Name:</b>	Not applicable.
<b>Transport Hazard Class(es):</b>	Not applicable.
<b>Packing Group:</b>	Not applicable.
<b>Department of Transportation:</b>	Not regulated as a hazardous material.
<b>International Air Transport Association (IATA):</b>	Not regulated as a dangerous good.
<b>International Maritime Dangerous Good (IMDG):</b>	Not regulated as a dangerous good.

**15. Regulatory Information**

**US Federal Regulations:**

<b>Toxic Substance Control Act (TSCA):</b>	Not listed.
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<b>CERCLA Hazardous Substance and Reportable Quantity:</b>	Not listed.
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<b>SARA 313:</b>	Not listed.
<b>SARA 302:</b>	Not listed.

**State Regulations**

<b>California Proposition 65:</b>	Not listed.
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**16. Other Information**

Not made with natural rubber latex.

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