Manufacturer: Akorn Incorporated
150 South Wyckles Road
Decatur, IL 62522
Contact Telephone: 1-800-932-5676
Email: customer.service@akorn.com

Section 1 – IDENTIFICATION

Common/Trade Name: METHYLERGONOVINE MALEATE INJECTION USP

Chemical Names: ergoline-8-carboxamide, 9,10-didehydro-N-[1-(hydroxymethyl)propyl]-6-methyl-, [8β(S)], (Z)-2-butenedioate (1:1) (salt)

Identified Use: Methylergonovine Maleate Injection USP is a semi-synthetic ergot alkaloid used for the prevention and control of postpartum hemorrhage. Prescription only. Sterile.

Section 2 – HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

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.

Route(s) of Entry: Absorption may occur through the skin or eyes. Exposure due to inhalation or ingestion is unlikely.

Signs and Symptoms of Exposure: 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.

Listed Carcinogenicity: NTP – No
IARC – No
OSHA – No

Target Organ(s): Female reproductive system

Medical Conditions Aggravated by Exposure: Individuals with hypertension, pregnancy, toxemia, or sensitivity to methylergonovine maleate.
**Section 3 – COMPOSITION/INFORMATION ON INGREDIENTS**

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS #</th>
<th>Concentration</th>
<th>OSHA PEL</th>
<th>ACGIH TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylergonovine Maleate, USP</td>
<td>57432-61-8</td>
<td>0.2 mg/mL</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Maleic Acid, EP</td>
<td>110-16-7</td>
<td>0.10 mg/mL</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
<tr>
<td>Sodium Chloride, USP</td>
<td>7647-14-5</td>
<td>7.0 mg/mL</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
<tr>
<td>Water for Injection, USP</td>
<td>7732-18-5</td>
<td>QS</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
</tbody>
</table>

**Section 4 – FIRST AID MEASURES**

**Eyes:** Flush thoroughly with copious amounts of water for at least 15 minutes and consult a physician.

**Skin:** Remove contaminated clothing. Wash thoroughly with warm water and soap for at least 15 minutes. Seek medical attention if irritation or other symptoms develop.

**Ingestion:** If ingestion occurs, seek medical attention immediately.

**Inhalation:** If difficulty breathing occurs, seek medical attention immediately. If not breathing, provide artificial respiration.

**Note to Physician:** Overdose should be treated symptomatically. See package insert.

**Section 5 – FIRE FIGHTING MEASURES**

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

**For firefighters** Evacuate personnel. Wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**Unusual Fire/Explosion Hazards:** None
Section 6 – ACCIDENTAL RELEASE MEASURES

**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.

**Personal Precautions**
Wear appropriate personal protective equipment in cases where exposure may occur, including gloves, lab coat and eye protection. Additional protective equipment may be required, including use of respiratory protection.

**Methods for Clean-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.

Section 7 – HANDLING AND STORAGE

**Handling**
Handle with substance only in original and closed package. Avoid dust formation. Avoid contact with skin and eyes.

**Storage**
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.

Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

**Special Requirements**
After handling, wash hands thoroughly.

**Personal Protective Equipment**

**Respiratory Protection**
Under normal conditions of product use, respiratory protection should not be required if used in an area with adequate ventilation. Large spills or generation of dust may require the use of approved air-purifying respirators or self-contained breathing apparatus (SCBA)

**Eye Protection**
Approved safety goggles/glasses.

**Skin and Body Protection**
Use latex or nitrile gloves. Lab Coat
Section 9 – PHYSICAL/CHEMICAL CHARACTERISTICS

Methylergonovine Maleate Injection USP, 0.2 mg/mL is supplied as a 1 mL aqueous solution contained in an amber ampule.

- **Appearance**: Clear, colorless liquid
- **Odor**: Odorless
- **Flash Point**: Not Applicable
- **Auto-ignition Temperature**: Not Applicable
- **VOC Content**: No information available
- **Solubility**: Soluble in Water
- **Specific Gravity**: Approximate to water
- **Vapor Density**: Approximate to water
- **Relative Density**: Approximate to water
- **Boiling Point/Range**: Approximate to water
- **Vapor Pressure**: Approximate to water
- **Viscosity**: Approximate to water
- **Water Solubility**: Soluble in water
- **Evaporation Rate**: Approximate to water
- **Latex Free**: Yes

Section 10 – STABILITY AND REACTIVITY

- **Stability**: Stable under normal conditions
- **Incompatibility**: Macrolide antibiotics and protease inhibitors
- **Conditions to Avoid**: High temperature, Light, Freezing
- **Materials to Avoid**: Strong oxidizing agents
- **Hazardous Decomposition Products**: Under fire condition emits toxic fumes and gases – carbon monoxide, carbon dioxide and nitrous oxides
- **Hazardous Polymerization**: Does not occur

Section 11 – TOXICOLOGICAL INFORMATION

- **LD₅₀ oral, rat**: 93 to 105 mg/kg
- **LD₅₀ oral, mouse**: 187 mg/kg
- **Sensitization**: Can influence allergic reactions in sensitive individuals
- **Eyes**: Irritant
- **Skin**: Irritant
- **Carcinogenicity**: Long term studies in animals show no carcinogenic potential.
- **Reproductive Toxicity**: 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.
Therapeutic side effects include 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 severe cases followed by hypotension, respiratory depression, hypothermia, convulsions, and coma.

Section 12 – ECOLOGICAL INFORMATION

Ecotoxicity
Under normal conditions of use, this material is not anticipated to have a significant impact on the environment.

Persistence and Degradability
No information available

Bioaccumulation
No information available

Mobility
No information available

Section 13 – DISPOSAL INFORMATION

Waste from Residues/Unused
Dispose of in compliance with local, state and federal regulations

Contaminated Packaging
Dispose of as contaminated residue.

Section 14 – TRANSPORTATION INFORMATION

ADR
Not Regulated

DOT Hazardous Material
No

ICAO / IATA Status
Not Regulated

IMDG / IMO
Not regulated

RID
Not Regulated

Section 15 – REGULATORY INFORMATION

AICS
Listed

California Proposition 65 Status
Not Listed

CERCLA
Not Listed

DSL/NDSL
Not Listed

EINECS/ELINCS
Listed

ENCS
Not Listed

EPA/RCRA Status
Not Listed

IECSC
Not Listed

KECL
Not Listed

PICCS
Listed

SARA Title III Section 313
Not listed

TSCA Status
Not Listed
Section 16 – OTHER INFORMATION

LEGEND
A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS
A.D.R. - INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD
AICS - Australian Inventory of Chemical Substances
DOT – US Department of Transportation
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK
I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
I.A.T.A. – INTERNATIONAL AIR TRANSPORT ASSOCIATION – DANGEROUS GOODS REG.
IECSC - China Inventory of Existing Chemical Substances
I.M.D.G. - INTERNATIONAL MARITIME DANGEROUS GOODS CODE
KECL - Korean Existing and Evaluated Chemical Substances
N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
N.L.M. - NATIONAL LIBRARY OF MEDICINE
N.T.P. - NATIONAL TOXICOLOGY PROGRAM
PICCS - Philippines Inventory of Chemicals and Chemical Substances
R.I.D. - TRANSPORT OF DANGEROUS GOODS BY RAIL
R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

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