

# Methylergonovine Maleate Injection USP, 0.2 mg/mL

## Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations  
Revision Date: 08/14/2015 Date of issue: 08/14/2015

Version: 1.0

### SECTION 1: IDENTIFICATION

#### 1.1. Product Identifier

**Product Form:** Mixture

**Product Name:** Methylergonovine Maleate Injection USP, 0.2 mg/mL

**Product Code:** 0517-0740-20

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

#### 1.2. Intended Use of the Product

**Use of the substance/mixture:** A semi-synthetic ergot alkaloid used for the prevention and control of postpartum hemorrhage.

#### 1.3. Name, Address, and Telephone of the Responsible Party

##### Company

PharmaForce, Inc.  
6610 New Albany Road East  
New Albany, OH 43054  
T 614-436-2222  
[www.pharmaforceinc.com](http://www.pharmaforceinc.com)

##### Distributor

American Regent, Inc.  
One Luitpold Drive  
P.O. Box 9001  
Shirley, NY 11967  
1-800-645-1706  
[www.luitpold.com](http://www.luitpold.com)

#### 1.4. Emergency Telephone Number

**Emergency Number** : CHEMTREC 1-800-424-9300

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1. Classification of the Substance or Mixture

##### Classification (GHS-US)

Not classified

#### 2.2. Label Elements

##### GHS-US Labeling

No labeling applicable

#### 2.3. Other Hazards

Exposure is not recommended for individuals with hypertension or persons who are pregnant. Exposure to this product may result in adverse effects. Exposure may cause irritation, nausea, dizziness, and headache. Overexposure to the active ingredient by pregnant women may cause abortion or fetal harm. Refer to patient insert for more information.

#### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	99.27	Not classified
Sodium chloride	(CAS No) 7647-14-5	0.7	Not classified
Methylergometrine maleate	(CAS No) 57432-61-8	0.02	Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Repr. 2, H361
Maleic acid	(CAS No) 110-16-7	0.01	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317 STOT SE 3, H335

Full text of H-phrases: see section 16

### SECTION 4: FIRST AID MEASURES

#### 4.1. Description of First Aid Measures

**First-aid Measures General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.

# Methylergonovine Maleate Injection USP, 0.2 mg/mL

## Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

**First-aid Measures After Inhalation:** When symptoms occur: go into open air and ventilate suspected area. Seek medical attention if ill effect or irritation develops.

**First-aid Measures After Skin Contact:** Remove contaminated clothing. Flush with copious quantities of water for 15 minutes. Seek medical attention if ill effect or irritation develops.

**First-aid Measures After Eye Contact:** Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention if ill effect or irritation develops.

**First-aid Measures After Ingestion:** Rinse mouth. Do NOT induce vomiting. Seek medical attention.

### 4.2. Most important symptoms and effects, both acute and delayed

**Symptoms/Injuries:** When handling in workplace settings, in quantities that are most likely above the therapeutic dose, this product may be harmful if absorbed through the eyes, skin, or respiratory tract. Refer to patient insert for more information.

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** May cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause eye irritation.

**Symptoms/Injuries After Ingestion:** Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** Overexposure to the active ingredient by pregnant women may cause abortion or fetal harm. May cause oxytocic and uterotonic effects.

### 4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Water spray, dry chemical, foam, carbon dioxide.

**Unsuitable Extinguishing Media:** A heavy water stream may spread burning liquid. CAUTION: Carbon dioxide is an asphyxiant. Lack of oxygen can be fatal.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Not flammable.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Firefighting Instructions:** Exercise caution when fighting any chemical fire. Do not breathe fumes from fires or vapors from decomposition. Use water spray or fog for cooling exposed containers.

**Protection During Firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal Precautions, Protective Equipment and Emergency Procedures

**General Measures:** Avoid all unnecessary exposure. Do not breathe vapour or mist.

#### 6.1.1. For Non-emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE). Refer to section 8.2.

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Responders

**Protective Equipment:** Equip cleanup crew with proper protection.

**Emergency Procedures:** Ventilate area.

### 6.2. Environmental Precautions

Prevent entry to sewers and public waters.

### 6.3. Methods and Material for Containment and Cleaning Up

**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

**Methods for Cleaning Up:** Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

### 6.4. Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Use only as directed by the information identified in the package insert.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking, or smoking and again when leaving work.

# Methylergonovine Maleate Injection USP, 0.2 mg/mL

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

## 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Store in original container. Store in a dry, cool and well-ventilated place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

**Incompatible Products:** Strong bases. Strong oxidizers. Strong acids.

**Storage Temperature:** 20 - 25 °C (68 - 77 °F)

## 7.3. Specific End Use(s)

A semi-synthetic ergot alkaloid used for the prevention and control of postpartum hemorrhage.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

### 8.2. Exposure Controls

**Appropriate Engineering Controls** : Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

**Personal Protective Equipment** : Gloves. Protective clothing. Protective goggles.



**Hand Protection** : Wear chemically resistant protective gloves.

**Eye Protection** : Chemical goggles or safety glasses.

**Skin and Body Protection** : Wear suitable protective clothing. Wash contaminated clothing before reuse.

**Respiratory Protection** : In case of inadequate ventilation wear respiratory protection.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

<b>Physical State</b>	: Liquid
<b>Appearance</b>	: Clear, Colorless
<b>Odor</b>	: No Odor
<b>Odor Threshold</b>	: No data available
<b>pH</b>	: 2.7 - 3.5
<b>Evaporation Rate</b>	: No data available
<b>Melting Point</b>	: No data available
<b>Freezing Point</b>	: No data available
<b>Boiling Point</b>	: No data available
<b>Flash Point</b>	: Approx. to water
<b>Auto-ignition Temperature</b>	: No data available
<b>Decomposition Temperature</b>	: No data available
<b>Flammability (solid, gas)</b>	: No data available
<b>Vapor Pressure</b>	: No data available
<b>Relative Vapor Density at 20 °C</b>	: No data available
<b>Relative Density</b>	: No data available
<b>Specific Gravity</b>	: Approximate to water
<b>Solubility</b>	: Soluble in water
<b>Partition Coefficient: N-Octanol/Water</b>	: No data available
<b>Viscosity</b>	: No data available

**9.2. Other Information** No additional information available

## SECTION 10: STABILITY AND REACTIVITY

**10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.

**10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see Section 7).

**10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

# Methylergonovine Maleate Injection USP, 0.2 mg/mL

## Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

- 10.4. Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. Incompatible Materials:** Strong oxidizers. Strong bases. Strong acids.
- 10.6. Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO<sub>2</sub>). Sodium oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information On Toxicological Effects

**Acute Toxicity:** Not classified

Methylergometrine maleate (57432-61-8)	
LD50 Oral Rat	93 mg/kg
Maleic acid (110-16-7)	
LD50 Oral Rat	708 mg/kg
LD50 Dermal Rabbit	1560 mg/kg
LC50 Inhalation Rat	> 720 mg/m <sup>3</sup> (Exposure time: 1 h)
Sodium chloride (7647-14-5)	
LD50 Oral Rat	3 g/kg
LC50 Inhalation Rat	> 42 g/m <sup>3</sup> (Exposure time: 1 h)

**Skin Corrosion/Irritation:** Not classified

**pH:** 2.7 - 3.5

**Serious Eye Damage/Irritation:** Not classified

**pH:** 2.7 - 3.5

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Symptoms/Injuries After Inhalation:** May cause respiratory irritation.

**Symptoms/Injuries After Skin Contact:** May cause skin irritation.

**Symptoms/Injuries After Eye Contact:** May cause eye irritation.

**Symptoms/Injuries After Ingestion:** Potent pharmaceutical- ingestion may be harmful or have adverse effects.

**Chronic Symptoms:** Overexposure to the active ingredient by pregnant women may cause abortion or fetal harm. May cause oxytocic and uterotonic effects.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

Maleic acid (110-16-7)	
LC50 Fish 1	5 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
EC50 Daphnia 1	250 - 400 mg/l (Exposure time: 48 h - Species: Daphnia magna)
Sodium chloride (7647-14-5)	
LC50 Fish 1	5560 (5560 - 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flow-through])
EC50 Daphnia 1	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC 50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 2	340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

### 12.2. Persistence and Degradability

Methylergonovine Maleate Injection USP, 0.2 mg/mL	
Persistence and Degradability	Not established.

### 12.3. Bioaccumulative Potential

Methylergonovine Maleate Injection USP, 0.2 mg/mL	
Bioaccumulative Potential	Not established.
Maleic acid (110-16-7)	
BCF fish 1	10
Log Pow	-0.79 - 0.32

# Methylergonovine Maleate Injection USP, 0.2 mg/mL

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

<b>Sodium chloride (7647-14-5)</b>	
<b>BCF fish 1</b>	(no bioaccumulation)

**12.4. Mobility in Soil** No additional information available

**12.5. Other Adverse Effects**

**Other Information** : Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

**13.1. Waste treatment methods**

**Sewage Disposal Recommendations:** Do not empty into drains; dispose of this material and its container in a safe way.

**Waste Disposal Recommendations:** Dispose of waste material in accordance with all local, regional, national, and international regulations.

## SECTION 14: TRANSPORT INFORMATION

**14.1. In Accordance with DOT** Not regulated for transport

**14.2. In Accordance with IMDG** Not regulated for transport

**14.3. In Accordance with IATA** Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

**15.1 US Federal Regulations**

<b>Water (7732-18-5)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory
<b>Maleic acid (110-16-7)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory
<b>Sodium chloride (7647-14-5)</b>
Listed on the United States TSCA (Toxic Substances Control Act) inventory

**15.2 US State Regulations**

<b>Maleic acid (110-16-7)</b>
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

<b>Revision Date</b>	: 08/14/2015
<b>Other Information</b>	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

**GHS Full Text Phrases:**

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhalation) Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Repr. 2	Reproductive toxicity Category 2
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H301	Toxic if swallowed
H302	Harmful if swallowed
H311	Toxic in contact with skin
H312	Harmful in contact with skin
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation

# Methylergonovine Maleate Injection USP, 0.2 mg/mL

## Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

H331	Toxic if inhaled
H335	May cause respiratory irritation
H361	Suspected of damaging fertility or the unborn child

Refer to Luitpold/American Regent prescribing information for further information at: <http://americanregent.com/AllProducts.aspx>

*The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.*

SDS US (GHS HazCom)