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-(hydroxmethyl)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
American Regent, Inc.
5 Ramsey Road
P.O. Box 9001
Shirley, NY
1-800-645-1706
www.americanregent.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

<table>
<thead>
<tr>
<th>Name</th>
<th>Product Identifier (CAS No)</th>
<th>%</th>
<th>Classification (GHS-US)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>99.27</td>
<td>Not classified</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>0.7</td>
<td>Not classified</td>
</tr>
<tr>
<td>Methylergometrine maleate</td>
<td>57432-61-8</td>
<td>0.02</td>
<td>Acute Tox. 3 (Oral), H301 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Inhalation), H331 Repr. 2, H361</td>
</tr>
<tr>
<td>Maleic acid</td>
<td>110-16-7</td>
<td>0.01</td>
<td>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</td>
</tr>
</tbody>
</table>

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.
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.

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.
7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store in refrigerator, 2º to 8ºC (36º to 46ºF). Protect from light. Use carton to protect contents until used. Administer only if solution is clear and colorless.


7.3. Specific End Use(s)

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

SECTION 8: EXPOSURE CONTROLS/PERSOAL 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.


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

Physical State: Liquid

Appearance: Clear, Colorless

Odor: No Odor

Odor Threshold: No data available

pH: 2.7 - 3.5

Evaporation Rate: No data available

Melting Point: No data available

Freezing Point: No data available

Boiling Point: No data available

Flash Point: Approximate to water

Auto-ignition Temperature: No data available

Decomposition Temperature: No data available

Flammability (solid, gas): No data available

Vapor Pressure: No data available

Relative Vapor Density at 20 ºC: No data available

Relative Density: No data available

Specific Gravity: Approximate to water

Solubility: Soluble in water

Partition Coefficient: N-Octanol/Water: No data available

Viscosity: 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.
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, CO₂). Sodium oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. **Information On Toxicological Effects**

**Acute Toxicity:** Not classified

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Route</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methylergometrine maleate (57432-61-8)</td>
<td>LD50 Oral Rat</td>
<td>Rat</td>
<td>93 mg/kg</td>
</tr>
<tr>
<td>Maleic acid (110-16-7)</td>
<td>LD50 Oral Rat</td>
<td>Rat</td>
<td>708 mg/kg</td>
</tr>
<tr>
<td>Maleic acid (110-16-7)</td>
<td>LD50 Dermal Rabbit</td>
<td>Rabbit</td>
<td>1560 mg/kg</td>
</tr>
<tr>
<td>Maleic acid (110-16-7)</td>
<td>LC50 Inhalation Rat</td>
<td>Rat</td>
<td>&gt; 720 mg/m³ (Exposure time: 1 h)</td>
</tr>
<tr>
<td>Sodium chloride (7647-14-5)</td>
<td>LD50 Oral Rat</td>
<td>Rat</td>
<td>3 g/kg</td>
</tr>
<tr>
<td>Sodium chloride (7647-14-5)</td>
<td>LC50 Inhalation Rat</td>
<td>Rat</td>
<td>&gt; 42 g/m³ (Exposure time: 1 h)</td>
</tr>
</tbody>
</table>

**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.

**Chronic Symptoms:** Potent pharmaceutical ingestion may be harmful or have adverse effects. May cause oxytocic and uterotonic effects.

SECTION 12: ECOLOGICAL INFORMATION

12.1. **Toxicity**

**Maleic acid (110-16-7)**

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Species</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 Fish 1</td>
<td>EC50 Daphnia 1</td>
<td>Species: Pimephales promelas [static]</td>
<td>5 mg/l (Exposure time: 96 h)</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>LC50 Fish 1</td>
<td>Species: Daphnia magna</td>
<td>250 - 400 mg/l (Exposure time: 48 h)</td>
</tr>
</tbody>
</table>

**Sodium chloride (7647-14-5)**

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Species</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 Fish 1</td>
<td>EC50 Daphnia 1</td>
<td>Species: Lepomis macrochirus [flow-through]</td>
<td>5560 (5560 - 6080) mg/l (Exposure time: 96 h)</td>
</tr>
<tr>
<td>EC50 Daphnia 1</td>
<td>LC50 Fish 2</td>
<td>Species: Lepomis macrochirus [static]</td>
<td>1000 mg/l (Exposure time: 48 h)</td>
</tr>
<tr>
<td>LC 50 Fish 2</td>
<td>EC50 Daphnia 2</td>
<td>Species: Daphnia magna [Static]</td>
<td>12946 mg/l (Exposure time: 96 h)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>340.7 (340.7 - 469.2) mg/l (Exposure time: 48 h)</td>
</tr>
</tbody>
</table>

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

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

15.2 US State Regulations
Maleic acid (110-16-7)
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
Revision Date : 01/10/2019
Other Information : 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
- Rep. 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
- H331 Toxic if inhaled
**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

<table>
<thead>
<tr>
<th>Hazard Statement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
<tr>
<td>H361</td>
<td>Suspected of damaging fertility or the unborn child</td>
</tr>
</tbody>
</table>

Refer to 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 American Regent, Inc., 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 American Regent, Inc. has been advised of the possibility of such damages.

SDS US (GHS HazCom)