AMERICAN REGEN LabORATORIES, INC.
MATERIAL SAFETY DATA SHEET

PRODUCT NAME: EPINEPhRINE INJECTION

MANUFACTURER: LUITPOLD PHARMACEUTICALS, INC.
ONE LUITPOLD DRIVE
SHIRLEY, NY 11967

EMERGENCY TELEPHONE NUMBER: (800) 645-1706

SECTION I: IDENTITY

Common Name - Epinephrine
Chemical Name - dihydroxy-a-(methylaminomethyl) benzyl alcohol
Chemical Family - Hemostatic Agent
Chemical Formula - \( C_{8}H_{13}NO_{3} \)
CAS No - 51-43-4
RTECS No - DO2625000

SECTION II: HAZARDOUS INGREDIENTS/ACTIVE INGREDIENTS

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>OSHA PEL</th>
<th>ACGIH TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epinephrine</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Hydrochloride</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

SECTION III: PHYSICAL & CHEMICAL CHARACTERISTICS

DESCRIPTION: Epinephrine Injection, USP is a sterile solution of Epinephrine HCl in Water for Injection (pH 2.2 - 5.0).

Appearance & Odor - Clear, colorless solution; odorless
Boiling Point - N/A
Solubility in Water - Slightly Soluble
Vapor Pressure - N/A
Vapor Density - N/A
SECTION IV: FIRE & EXPLOSION DATA

Flash Point - N/A
Extinguisher Media - Water spray, carbon dioxide, dry chemical, or foam as appropriate for surrounding fire and materials.

Flammable Limits - (LEL) - N/A
(UEL) - N/A

Unusual Fire and Explosion Hazards - Emits toxic fumes.

Hazardous Decomposition Products - Epinephrine emits toxic fumes when heated to decomposition (188°C).

Special Fire Fighting Procedures - Firefighters should use self-contained breathing apparatus and protective clothing.

SECTION V: REACTIVITY DATA

Stability - Stable

Conditions/Materials to Avoid - Exposure to light may cause decomposition. Do not mix with other drugs.

Hazardous Polymerization - Will not occur

SECTION VI: HEALTH HAZARD DATA

Primary Routes of Exposure - Inhalation, Ingestion, and Skin Absorption.

Chemical Listing as Carcinogen
National Toxicology Program - No
IARC Monographs - No
OSHA - No

--- MSDS TRACKING INFORMATION ---

WARACZYNISKI, MEG
UNIV OF WIS-DEPT PHYS
800 W MAIN/ROOM 4014
WHITEWATER, WI 53190

MID: 1050442 EPINEPHRINE INJ
PID: 1021957 CUST: 0172674-009
IMG: I:50442_2 PAGE: 2 of 4

PACKET: 52609-3021
Toxicity Data

LD₅₀:
- 62 mg/Kg skin-rat;
- 930 ug/Kg intravenous-rat;
- 3500 mg/Kg intramuscular-rat;
- 50 mg/Kg oral-mouse;
- 4 mg/Kg intraperitoneal-mouse;
- 2790 ug/Kg subcutaneous-mouse;
- 217 ug/Kg intravenous-mouse

Signs and Symptoms of Overexposure

Elevated arterial pressure causing vascular hemorrhage and pulmonary edema (can cause death).

Emergency & First Aid Procedures

Inhalation: Remove person to fresh air. Remove contaminated clothing. Seek medical attention.

Ingestion: Flush mouth out with water. Seek medical attention.

Skin Contact: Remove contaminated clothing. Flush area with water. Seek medical attention.

Eye Contact: Flush with water. Seek medical attention.

FOR ADDITIONAL INFORMATION, REFER TO THE PRODUCT INSERT.

SECTION VII: PROTECTIVE EQUIPMENT DATA

Ventilation - Local exhaust recommended

Respiratory - N/A, however, NIOSH-approved respirator should be available

Eyes - Safety Goggles

Gloves - Disposable surgical latex gloves

Clothing - Disposable protective apparel (protect exposed skin)
SECTION VIII: STORAGE & HANDLING DATA

Precautions - As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mists, and/or vapors associated with the product. Do not mix with other drugs.

SECTION IX: ACCIDENTAL SPILL PROCEDURES/WASTE DISPOSAL DATA

Containment/Clean-up - Wear recommended personal protective equipment. Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with paper towels. Wipe working surfaces to dryness, then wash with soap and water.

Waste Disposal - Dispose of in accordance with federal, state, and local regulations. Do not mix with other substances.

Shipping Information - Environmentally hazardous substance. Liquid, N.O.S. (contains epinephrine) 9, UN3082, PG III

NOTICE: The information contained herein is believed to be complete and accurate. However, it is the user’s responsibility to determine the suitability of the information for his or her particular purpose. Luitpold Pharmaceuticals, Inc. assumes no additional liability or responsibility resulting from the use of, or reliance on, this information.

Prepared by: ________________  Date: 9-4-96

Audrey Bialeski, Supervisor, Regulatory Affairs

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