Product Name: Erythromycin Lactobionate Inj. USP
Issued: 08-May-2003

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories
Hospital Products Division
200 Abbott Park Rd.
Abbott Park, Illinois 60064 - 6135

Customer Service Telephone: HPD : 1-800-222-6883
Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada) or (703) 527-3887
Product Name: Erythromycin Lactobionate Inj. USP
Synonyms: Erythrocin Lactobionate I.V. 1 gram per vial: Erythromycin Lactobionate for Injection, USP
List Number: 6342, 6365, 6368, 6476, 6478, 6481, 6482, 6483

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent</th>
<th>OSHA PEL</th>
<th>ACGIH TLV</th>
<th>AIHA WEEL</th>
<th>Abbott EEL</th>
<th>Skin Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>1.2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>10 ppm TWA; 44.2 mg/m³ TWA</td>
<td>Not Applicable</td>
<td>None</td>
</tr>
<tr>
<td>Erythromycin Lactobionate 3847-29-8</td>
<td>10</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>3 mg/m² TWA</td>
<td>Not Applicable</td>
<td>None</td>
</tr>
<tr>
<td>Water 7732-18-5</td>
<td>88</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>None</td>
</tr>
</tbody>
</table>

Notes: OSHA PEL: US Occupational Safety and Health Administration - Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.
Abbott EEL: Abbott Laboratories Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.
C: Ceiling Limit.

3. HAZARDS IDENTIFICATION

Emergency Overview:
White to off-white powder.
Slight-aromatic.
This material is not toxic by ingestion or dermal contact. Causes mild eye irritation.

Routes of Exposure:
Oral: Unlikely (intact container)
Dermal: Unlikely (intact container)
Inhalation: Unlikely (intact container)

Hazard Information:
Ingestion Rating: None.
Product Name: Erythromycin Lactobionate Inj. USP
Issued: 14-Nov-2000

Skin Absorption Rating: Not determined.
Inhalation Rating: Not determined.
Corrosiveness Rating: Not determined.
Skin Contact Rating: Not determined.
Skin Sensitization Rating: Not determined.
Eye Contact Rating: Not determined.
Target Organs: Digestive System, Liver.

Carcinogenicity Rating:

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent</th>
<th>OSHA:</th>
<th>NTP:</th>
<th>IARC:</th>
<th>ACGIH:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>1.2</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Erythromycin Lactobionate</td>
<td>10</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Water</td>
<td>88</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

NFPA Rating:
Health: 0

Signs and Symptoms: None known from occupational exposure. Clinical data suggests the following: vomiting, nausea, abdominal pain, diarrhea.

Medical Conditions Aggravated by Exposure: Data suggest any preexisting ailments in the following organs: gastrointestinal system, liver. Hypersensitivity to the material and/or similar materials.

4. FIRST AID MEASURES

Eye Contact: Remove from the source of exposure. Flush eyes with copious amounts of water. If irritation or redness persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. No known antidote.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. No known antidote.

Inhalation: Remove from source of exposure. If signs of irritation or toxicity occur seek medical attention. Provide symptomatic/supportive care as necessary. No known antidote.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. No known antidote.

5. FIRE FIGHTING MEASURES

FLAMMABILITY:

Flammability Class: Non-flammable.
Autoignition Temp. (°C): Not determined.

FIRE-FIGHTING INFORMATION:

Suitable Extinguishing Media: Use appropriate medium for the underlying cause of the fire.
Special Protective Equipment: Wear protective clothing and self-contained breathing apparatus.
6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting: Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.

Personal Precautions: Use personal protective equipment identified in Section 8.

Environmental Precautions: Not determined.

7. HANDLING AND STORAGE

Handling: No special handling required.


Special Precautions: Not applicable.

8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: Respiratory protection is not needed during normal product use.

Eyes: Eye protection not required during typical product use conditions. Recommended if eye contact is likely.

Gloves: Impervious gloves.

Other Personal Protection Data: Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White to off-white powder.
Odor: Slight-aromatic.
Boiling Point @ 760 mm Hg (°C): Not determined.
Melting/Freezing Point (°C): Not determined.
Vapor Pressure (mm Hg): Not determined.
Bulk Density at 20°C: Not determined.
Solubility: Soluble in: water, 0.9% sodium chloride, dextrose solution.
Specific Gravity: Not determined.
pH: 6.5 - 7.5 (reconstituted)
Viscosity (centipoise): Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Not determined.
Self-Heating Tendency: Not determined.
Materials to Avoid: Not determined.
Product Name: Erythromycin Lactobionate Inj. USP
Issued: 14-Nov-2000

Hazardous Decomposition Products: Not determined.

Hazardous Polymerization: Not determined.

Conditions to Avoid: Not determined.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: Data for component (s) given below.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent</th>
<th>Acute Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>1.2</td>
<td>LD50 =</td>
<td>1040-3100</td>
<td>mg/kg</td>
<td>Animals</td>
</tr>
<tr>
<td>Erythromycin Lactobionate</td>
<td>10</td>
<td>LD50 &gt;</td>
<td>4000</td>
<td>mg/kg</td>
<td>Rats</td>
</tr>
</tbody>
</table>

Acute Toxicity - Dermal: Data for component (s) given below.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent</th>
<th>Acute Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>1.2</td>
<td>LD50 =</td>
<td>2000</td>
<td>mg/kg</td>
<td>Rabbits</td>
</tr>
</tbody>
</table>

Acute Toxicity - Inhalation: Data for component (s) given below.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent</th>
<th>Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>1.2</td>
<td>LC 50 =</td>
<td>2000</td>
<td>ppm</td>
<td>Rats</td>
</tr>
</tbody>
</table>

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Macrolide antibiotics are reported to be mild eye irritants.

Sensitization: May produce allergic response in individuals sensitive to erythromycins.

Target Organ Effects: In clinical use target organ effects include: gastrointestinal tract, liver.

Reproductive Effects: Not determined.

Carcinogenicity: Data for components given below.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent</th>
<th>Site of Tumors</th>
<th>Species</th>
<th>Dosage</th>
<th>Units</th>
<th>Route</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>1.2</td>
<td>None.</td>
<td>Animals</td>
<td>200</td>
<td>mg/kg</td>
<td>Oral</td>
<td>Unspecified</td>
</tr>
</tbody>
</table>

Mutagenicity: Not determined.

Notes:
1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined.

Biodegradation: Not determined.
Product Name: Erythromycin Lactobionate Inj. USP
Issued: 14-Nov-2000

General Notes: None.

Notes:
1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

### 13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: Disposal should be made in accordance with federal, state and local regulations.

### 14. TRANSPORT INFORMATION

**DOT:**
- Status: Not Regulated.

**ICAO/IATA:**
- Status: Not Regulated.

**IMDG:**
- Status: Not Regulated.

**TDG (Canada):**
- Status: Not Regulated.

### 15. REGULATORY INFORMATION

**SARA 313 Information**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Percent</th>
<th>SARA 313 Chemical:</th>
<th>CERCLA RQ/SARA EHS RQ (lbs):</th>
<th>SARA EHS TPQ (lbs):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>1.2</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Erythromycin Lactobionate</td>
<td>10</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Water</td>
<td>88</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**SARA 311/312 Hazard Catagories:**

- **Immediate Health:** Not determined.
- **Delayed Health:** Not determined.
- **Fire:** Not determined.
- **Sudden Pressure:** Not determined.
- **Reactivity:** Not determined.

**TSCA Inventory Status:** Not determined.

**CERCLA Status:** Not determined.

**RCRA Status:** Not determined.

**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.
Product Name: Erythromycin Lactobionate Inj. USP
Issued: 14-Nov-2000

EC HAZARD CLASSIFICATION:

Category of Danger: None
Indication of danger: Not dangerous goods
ICH Classification: Class 5 - Significant effects to animals and humans.

CANADIAN REGULATIONS:

Canadian Inventory: Not determined.
Canadian NDSL: Not determined.
WHMIS Hazard Class: Not determined.

Notes:
1. SARA = Superfund Amendments and the Reauthorization Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
7. ICH = International Committee for Harmonization.

16. OTHER INFORMATION

Document Authored By: Dan L. Furlan

Disclaimer:
The information and recommendations contained herein are based upon tests believed to be reliable. However, Abbott Laboratories does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.