SAFETY DATA SHEET

Product Name: Erythrocin Lactobionate-IV (erythromycin lactobionate for injection, USP)

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address
Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency 224 212-2000

Product Name
Erythrocin Lactobionate-IV (erythromycin lactobionate for injection, USP)

Synonyms
Erythromycin mono (4-0-β-D-galactopyranosyl-D-gluconate) (salt)

2. HAZARD(S) IDENTIFICATION

Emergency Overview
Erythrocin Lactobionate-IV (erythromycin lactobionate for injection, USP) is a powder containing lyophilized erythromycin lactobionate, a salt of the macrolide antibiotic erythromycin. Clinically, erythromycin lactobionate is used to treat infections due to susceptible organisms. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the liver, cardiovascular system and the auditory system (hearing).

U.S. OSHA GHS Classification

Physical Hazards
Hazard Class: Not Classified
Hazard Category: Not Classified

Health Hazards
Hazard Class: Eye Damage / Irritation
Hazard Category: 2B

Label Element(s)

Pictogram
NA

Signal Word
Warning

Hazard Statement(s)
Causes eye irritation

Precautionary Statement(s)

Prevention
Do not breathe vapor or spray
Wash hands thoroughly after handling

Response
Get medical attention if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythromycin Lactobionate</td>
<td>100</td>
<td>3847-29-8</td>
<td>OD7320000</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

Eye 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.

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.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this product. However, many organic dusts will combust at elevated temperatures.

Fire & Explosion Hazard
None anticipated for this product. Avoid the generation of dusty environments.

Extinguishing Media
As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures
No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
For spilled powder, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Absorb any liquid with an inert absorbent material (e.g. absorbent pad). Dispose of materials according to the applicable federal, state, or local regulations.

If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling
No special handling required under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions
No special precautions required for hazard control.
Product Name: Erythrocin Lactobionate-IV (erythromycin lactobionate for injection, USP)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>AIHA WEEL</th>
<th>Hospira EEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythromycin Lactobionate</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: 3 mg/m³ as erythromycin</td>
<td>8-hr TWA: Not Established</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: Workplace Environmental Exposure Level  
EEL: Employee Exposure Limit  
TWA: 8-hour Time Weighted Average

Respiratory Protection

Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or Aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin Protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye Protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>White to off-white powder</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>6.5 to 7.5 for a 2% aqueous solution</td>
</tr>
<tr>
<td>Melting point/Freezing Point</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range</td>
<td>NA</td>
</tr>
<tr>
<td>Flash Point</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density (Air =1)</td>
<td>NA</td>
</tr>
<tr>
<td>Relative Density</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility</td>
<td>NA</td>
</tr>
<tr>
<td>Partition Coefficient: n-octanol/water</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition Temperature</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>NA</td>
</tr>
<tr>
<td>Viscosity</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Erythrocin Lactobionate-IV (erythromycin lactobionate for injection, USP)

10. STABILITY AND REACTIVITY

- **Reactivity**: Not determined.
- **Chemical Stability**: Stable under standard use and storage conditions.
- **Hazardous Reactions**: Not determined
- **Conditions to Avoid**: Not determined
- **Incompatibilities**: Not determined
- **Hazardous Decomposition Products**: Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
- **Hazardous Polymerization**: Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

**Acute Toxicity** - Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythromycin Lactobionate</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>735</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
</tbody>
</table>

LD 50: Dosage that produces 50% mortality.

- **Occupational Exposure Potential**: Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
- **Signs and Symptoms**: None anticipated from normal handling of this product. In the workplace, erythromycin base and some salts have been reported to be irritating to the eyes and respiratory tract. In clinical use, adverse effects may include abdominal pain and cramps, nausea, vomiting, and diarrhea, most frequently. Hepatic dysfunction has been reported occasionally. Erythromycin has been associated with QT prolongation and ventricular arrhythmias, including ventricular tachycardia and torsades de pointes. Reversible high frequency loss has been reported with erythromycin in patients with renal insufficiency. Transient deafness has been reported following daily therapy of 4 grams or more. Allergic reactions (mostly rashes, pruritus, and urticaria; infrequently anaphylactoid/respiratory) have been clinically evident in < 0.05% of treated patients. Prolonged therapy can result in overgrowth of non-susceptible bacteria/fungi.
- **Aspiration Hazard**: None anticipated from normal handling of this product.
- **Dermal Irritation/Corrosion**: None anticipated from normal handling of this product.
- **Ocular Irritation/Corrosion**: None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.
- **Dermal or Respiratory Sensitization**: None anticipated from normal handling of this product. In clinical use, allergic reactions, ranging from urticaria to anaphylaxis, have occurred. Skin reactions ranging from mild eruptions to erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported rarely.
- **Reproductive Effects**: None anticipated from normal handling of this product. There was no apparent effect on male or female fertility in rats fed erythromycin (base) at levels up to 0.25% of diet. There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% of diet) prior to and during mating, during gestation, and through weaning of two successive litters.
- **Mutagenicity**: Mutagenicity studies have not been conducted.
11. TOXICOLOGICAL INFORMATION: continued

Carcinogenicity
Long-term animal data with erythromycin lactobionate for use in determination of possible carcinogenic effects are not available. However, long-term oral studies in rats with erythromycin ethylsuccinate and erythromycin base did not provide evidence of tumorigenicity.

Carcinogen Lists
IARC: Not listed  NTP: Not listed  OSHA: Not listed

Specific Target Organ Toxicity
– Single Exposure
NA

Specific Target Organ Toxicity
– Repeat Exposure
Based on clinical use, possible target organs include the liver, cardiovascular system and the auditory system (hearing).

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product.

Persistence/Biodegradability
Not determined for product.

Bioaccumulation
Not determined for product.

Mobility in Soil
Not determined for product.

Notes:

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS
Not regulated

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

ICAO/IATA STATUS
Not regulated

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

IMDG STATUS
Not regulated

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

Notes: DOT - US Department of Transportation Regulations
## 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exempt</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>


### GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Prevention**
- Do not breathe vapor or spray
- Wash hands after handling

**Response**
- Get medical attention if you feel unwell.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

### EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

<table>
<thead>
<tr>
<th>Classification(s)</th>
<th>Symbol</th>
<th>Indication of Danger</th>
<th>Risk Phrases</th>
<th>Safety Phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>S23: Do not breathe vapor/spray</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>S24: Avoid contact with the skin</td>
<td>S25: Avoid contact with eyes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>S37/39 Wear suitable gloves and eye/face protection</td>
<td></td>
</tr>
</tbody>
</table>
16. OTHER INFORMATION

Notes:

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH TLV</td>
<td>American Conference of Governmental Industrial Hygienists – Threshold Limit Value</td>
</tr>
<tr>
<td>CAS</td>
<td>Chemical Abstracts Service Number</td>
</tr>
<tr>
<td>CERCLA</td>
<td>US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act</td>
</tr>
<tr>
<td>DOT</td>
<td>US Department of Transportation Regulations</td>
</tr>
<tr>
<td>EEL</td>
<td>Employee Exposure Limit</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>LD₅₀</td>
<td>Dosage producing 50% mortality</td>
</tr>
<tr>
<td>NA</td>
<td>Not applicable/Not available</td>
</tr>
<tr>
<td>NE</td>
<td>Not established</td>
</tr>
<tr>
<td>NIOSH</td>
<td>National Institute for Occupational Safety and Health</td>
</tr>
<tr>
<td>OSHA PEL</td>
<td>US Occupational Safety and Health Administration – Permissible Exposure Limit</td>
</tr>
<tr>
<td>Prop 65</td>
<td>California Proposition 65</td>
</tr>
<tr>
<td>RCRA</td>
<td>US EPA, Resource Conservation and Recovery Act</td>
</tr>
<tr>
<td>RTECS</td>
<td>Registry of Toxic Effects of Chemical Substances</td>
</tr>
<tr>
<td>SARA</td>
<td>Superfund Amendments and Reauthorization Act</td>
</tr>
<tr>
<td>STEL</td>
<td>15-minute Short Term Exposure Limit</td>
</tr>
<tr>
<td>STOT - SE</td>
<td>Specific Target Organ Toxicity – Single Exposure</td>
</tr>
<tr>
<td>STOT - RE</td>
<td>Specific Target Organ Toxicity – Repeated Exposure</td>
</tr>
<tr>
<td>TSCA</td>
<td>Toxic Substance Control Act</td>
</tr>
<tr>
<td>TWA</td>
<td>8-hour Time Weighted Average</td>
</tr>
</tbody>
</table>

MSDS Coordinator: Hospira GEHS
Date Prepared: October 18, 2012
Date Revised: June 02, 2014

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