

SAFETY DATA SHEET

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

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Hospira, Inc.

Address 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 Hazard Category

Not Classified Not Classified

Health Hazards Hazard Class Hazard Category

Eye Damage / Irritation 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

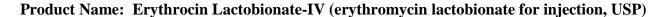
Wash hands thoroughly after handling

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

Active Ingredient NameErythromycin LactobionateChemical Formula $C_{37}H_{67}NO_{13} \bullet C_{12}H_{22}O_{12}$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Erythromycin Lactobionate	100	3847-29-8	OD7320000

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

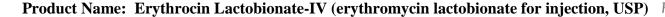
Handling No special handling required under conditions of normal product use.

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.





8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Erythromycin Lactobionate	8-hr TWA: Not	8-hr TWA: Not	8-hr TWA: 3 mg/m3	8-hr TWA: Not
	Established	Established	as erythromycin	Established

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

Appearance/Physical State White to off-white powder

Odor NA
Odor Threshold NA

pH 6.5 to 7.5 for a 2% aqueous solution

NA Melting point/Freezing Point **Initial Boiling Point/Boiling Point Range** NA NA **Flash Point Evaporation Rate** NA Flammability (solid, gas) NA **Upper/Lower Flammability or Explosive Limits** NA Vapor Pressure NA Vapor Density (Air =1) NA **Relative Density** NA **Solubility** NA Partition Coefficient: n-octanol/water NA **Auto-ignition Temperature** NA

Decomposition Temperature

Viscosity

NA NA

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10. STABILITY AND REACTIVITY

Reactivity Not determined.

Stable under standard use and storage conditions. **Chemical Stability**

Not determined **Hazardous Reactions** Not determined **Conditions to Avoid 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).

Not anticipated to occur with this product. **Hazardous Polymerization**

11. TOXICOLOGICAL INFORMATION

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

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Erythromycin Lactobionate	100	LD50	Intraperitoneal	735	mg/kg	Mouse

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 OT 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.

None anticipated from normal handling of this product. **Aspiration Hazard**

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.

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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 NA

Specific Target Organ Toxicity

- Single Exposure

Based on clinical use, possible target organs include the liver, cardiovascular system

- **Repeat Exposure** 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

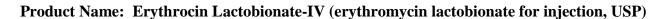
ICAO/IATA STATUS Not regulated

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

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

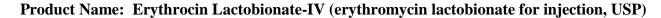
Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

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.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement		
NA	NA	NA	NA	NA		
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.					
Classification(s)	NA					
Symbol	NA					
Indication of Danger	NA					
Risk Phrases	NA					
Safety Phrases	S23: Do not breathe v	apor/spray				

S37/39 Wear suitable gloves and eye/face protection.





16. OTHER INFORMATION

Notes:

ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value

CAS Chemical Abstracts Service Number

CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act

DOT US Department of Transportation Regulations

EEL Employee Exposure Limit

 $\begin{array}{ll} \text{IATA} & \text{International Air Transport Association} \\ \text{LD}_{50} & \text{Dosage producing 50\% mortality} \\ \text{NA} & \text{Not applicable/Not available} \\ \end{array}$

NE Not established

NIOSH National Institute for Occupational Safety and Health

OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit

Prop 65 California Proposition 65

RCRA US EPA, Resource Conservation and Recovery Act
RTECS Registry of Toxic Effects of Chemical Substances
SARA Superfund Amendments and Reauthorization Act

STEL 15-minute Short Term Exposure Limit

STOT - SE Specific Target Organ Toxicity – Single Exposure STOT - RE Specific Target Organ Toxicity – Repeated Exposure

TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

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

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