



# SAFETY DATA SHEET

Revision date 13-Jun-2025

Version 4

Page 1 / 10

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

**Product Name** Erythrocin(TM) Lactobionate-IV (Hospira, Inc.)  
**Product Code(s)** PZ03419  
**Synonyms** Erythromycin Lactobionate  
**Trade Name:** Erythrocin(TM)  
**Chemical Family:** Not determined

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Pharmaceutical product used as antibiotic agent

### 1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
Ireland  
+353 21 4378701

**E-mail address** pfizer-MSDS@pfizer.com

### 1.4. Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Respiratory sensitization**

Category 1 - (H334)

**Skin sensitization**

Category 1 - (H317)

### **OSHA Classification**

**Hazards not otherwise classified (HNOC)**

Not applicable

**Hazards classified under paragraph (d)(1)(ii) of 1910.1200**

Not applicable

### 2.2. Label elements



# SAFETY DATA SHEET

Product Name Erythrocin(TM) Lactobionate-IV (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 2 / 10  
Version 4

**Signal word** Danger  
**Hazard statements** H317 - May cause an allergic skin reaction  
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

**Precautionary Statements - EU (§28, 1272/2008)** P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P272 - Contaminated work clothing should not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P284 - In case of inadequate ventilation wear respiratory protection  
P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing  
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician  
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
P362 + P364 - Take off contaminated clothing and wash it before reuse  
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable  
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

## 2.3. Other hazards Other hazards

An Occupational Exposure Value has been established for this substance ( see Section 8 ).

**PBT & vPvB** The product does not contain any substance(s) classified as PBT or vPvB.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## **Section 3: COMPOSITION/INFORMATION ON INGREDIENTS**

### 3.1 Substances

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Erythromycin Lactobionate (CAS #: 3847-29-8)	100		223-348-7	Resp. Sens.1 (H334) Skin Sens.1 (H317)	Not classified	No data available	No data available

**Full text of H- and EUH-phrases: see section 16**

Acute Toxicity Estimate No information available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No.

# SAFETY DATA SHEET

Product Name Erythrocin(TM) Lactobionate-IV (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 3 / 10  
Version 4

1907/2006 (REACH), Article 59).

## Additional information

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

### 4.2. Most important symptoms and effects, both acute and delayed

<b>Most important symptoms and effects</b>	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
--	--

### 4.3. Indication of any immediate medical attention and special treatment needed

<b>Note to physicians</b>	None.
---------------------------	-------

## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

<b>Suitable Extinguishing Media</b>	Dry chemical, CO2, alcohol-resistant foam or water spray.
-------------------------------------	---

### 5.2. Special hazards arising from the substance or mixture

<b>Specific hazards arising from the chemical</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Hazardous combustion products</b>	Formation of toxic gases is possible during heating or fire. May include oxides of nitrogen carbon
<b>Explosion data</b>	
<b>Sensitivity to mechanical impact</b>	No information available.
<b>Sensitivity to static discharge</b>	No information available.

### 5.3. Advice for firefighters

<b>Special protective equipment and precautions for fire-fighters</b>	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.
---	--

## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

<b>Personal precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see
-----------------------------	---

# SAFETY DATA SHEET

Product Name Erythrocin(TM) Lactobionate-IV (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 4 / 10  
Version 4

**For emergency responders** Section 8). Minimize exposure.  
Use personal protection recommended in Section 8.

## 6.2. Environmental precautions

**Environmental precautions** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

## 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.  
**Methods for cleaning up** Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface thoroughly.  
**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

## 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### 7.1. Precautions for safe handling

**Advice on safe handling** Minimize dust generation and accumulation. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage Conditions** Store as directed by product packaging.

### 7.3. Specific end use(s)

**Specific use(s)** Pharmaceutical product.

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### 8.1. Control parameters

**Erythromycin Lactobionate**  
Pfizer OEL TWA-8 Hr: 100 µg/m<sup>3</sup>

### 8.2. Exposure controls

# SAFETY DATA SHEET

Product Name Erythrocin(TM) Lactobionate-IV (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 5 / 10  
Version 4

<b>Engineering controls</b>	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.
<b>Personal protective equipment</b>	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
<b>Eye/face protection</b>	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
<b>Hand protection</b>	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
<b>Skin and body protection</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
<b>Respiratory protection</b>	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.).
<b>Thermal hazards</b>	No information available.
<b>Environmental exposure controls</b>	No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Powder
<b>Color</b>	White to off-white
<b>Odor</b>	No information available.
<b>Odor threshold</b>	No information available
<b>Property</b>	<b>Values</b>
<b>Melting point / freezing point</b>	No data available
<b>Boiling point or initial boiling point and boiling range</b>	No data available
<b>Flammability (solid, gas)</b>	No data available
<b>Lower and upper explosion limit/flammability limit</b>	
Lower explosion limit	No data available
Upper explosion limit	No data available
<b>Flash point</b>	No data available
<b>Autoignition temperature</b>	No data available
<b>Decomposition temperature</b>	
SADT (°C)	No data available
<b>pH</b>	6.5-7.5
pH (as aqueous solution)	No data available
<b>Kinematic viscosity</b>	No data available
Dynamic viscosity	No data available
<b>Solubility</b>	No data available
<b>Vapor pressure</b>	No data available

# SAFETY DATA SHEET

Product Name Erythrocin(TM) Lactobionate-IV (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 6 / 10  
Version 4

Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

## Partition Coefficient: (Method, pH, Endpoint, Value)

### Erythromycin

Predicted Log P 1.093

## 9.2. Other information

### Molecular formula

C37H67NO13.C12H22O12

### Molecular weight

1092.22

### 9.2.1. Information with regard to physical hazard classes

No information available

### Oxidizing properties

None

### 9.2.2. Other safety characteristics

No information available

## Section 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

#### Reactivity

No information available.

### 10.2. Chemical stability

#### Stability

Stable under normal conditions.

#### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

### Hazardous polymerization

Will not occur.

### 10.4. Conditions to avoid

#### Conditions to avoid

Fine particles (such as dust and mists) may fuel fires/explosions.

### 10.5. Incompatible materials

#### Incompatible materials

As a precautionary measure, keep away from strong oxidizers.

### 10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### **General Information:**

The information in this section describes the hazards of various forms of the active ingredient.

#### **Short term**

Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.

#### **Long Term:**

Animal studies indicate that this material may cause adverse effects on the liver the developing fetus.

# SAFETY DATA SHEET

Product Name Erythrocin(TM) Lactobionate-IV (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 7 / 10  
Version 4

**Known Clinical Effects:** Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. Clinical use of this drug has caused liver effects effects on hearing skin rash and gastrointestinal disturbances. Serious allergic reactions, including anaphylaxis, have been reported. While this compound causes birth defects in animal studies, experience in humans has not shown increased birth defects in infants born to mothers treated with this compound during pregnancy.

<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

## Acute Toxicity: (Species, Route, End Point, Dose)

### Erythromycin Lactobionate

Mouse IP LD50 735 mg/kg

### Erythromycin

Rat Oral LD 50 9272 mg/kg

Mouse Oral LD 50 2929 mg/kg

Mouse Intravenous LD 50 426 mg/kg

## Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

### Erythromycin

Embryo / Fetal Development Rat Oral 6000 mg/kg LOAEL Teratogenic

Embryo / Fetal Development Rat Subcutaneous 50 mg/kg LOAEL Teratogenic

Embryo / Fetal Development Mouse Oral 12,000 mg/kg LOAEL Teratogenic

**Carcinogenicity** Not listed as a carcinogen by IARC, NTP or US OSHA.

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

### 11.2.2. Other information

**Other adverse effects** No information available.

## **Section 12: ECOLOGICAL INFORMATION**

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

### 12.1. Toxicity

# SAFETY DATA SHEET

Product Name Erythrocin(TM) Lactobionate-IV (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 8 / 10  
Version 4

## 12.2. Persistence and degradability

**Persistence and degradability** No information available.

## 12.3. Bioaccumulative potential

**Bioaccumulation**

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Erythromycin**

Predicted Log P 1.093

## 12.4. Mobility in soil

**Mobility in soil** No information available.

## 12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment** Based on available data, the classification criteria are not met.

## 12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

## 12.7. Other adverse effects

**Other adverse effects** No information available.

**PMT or vPvM properties** Based on available data, the classification criteria are not met.

Chemical name	PMT and vPvM assessment
Erythromycin	PMT & vPvM

## **Section 13: DISPOSAL CONSIDERATIONS**

### 13.1. Waste treatment methods

#### **Waste from residues/unused products**

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## **Section 14: TRANSPORT INFORMATION**

The following refers to all modes of transportation unless specified below.

**Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.**



# SAFETY DATA SHEET

Product Name Erythrocin(TM) Lactobionate-IV (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 9 / 10  
Version 4

**UN number:** Not applicable  
**UN proper shipping name:** Not applicable  
**Transport hazard class(es):** Not applicable  
**Packing group:** Not applicable  
**Environmental Hazard(s):** Not applicable

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Erythromycin Lactobionate

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	223-348-7
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 4

#### National regulations

##### Germany

**Chemical Prohibition Ordinance (ChemVerbotsV)**

Not applicable

##### **TRGS 905**

Not applicable

##### Switzerland

<b>Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018</b>	Not applicable
<b>Storage of Hazardous Material</b>	Not applicable
<b>WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20</b>	Not applicable
<b>Major Accidents Ordinance SR 814.012</b>	Not applicable

##### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

##### **Authorizations and/or restrictions on use:**

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

##### **Persistent Organic Pollutants**

Not applicable

##### **Ozone-depleting substances (ODS) Regulation (EU) 2024/590**

Not applicable.

# SAFETY DATA SHEET

Product Name Erythrocin(TM) Lactobionate-IV (Hospira, Inc.)  
Revision date 13-Jun-2025

Page 10 / 10  
Version 4

## Explosives Precursors Marketing and Use (2019/1148)

Not applicable

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing Chemicals Inventory  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**NZIoC** - New Zealand Inventory of Chemicals  
**TCSI** - Taiwan Chemical Substance Inventory

## 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## **Section 16: OTHER INFORMATION**

### Key or legend to abbreviations and acronyms used in the safety data sheet

### **Full text of any hazard and/or precautionary statements referred to under Sections 2-15**

H317 - May cause an allergic skin reaction H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

**Data Sources:** The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

**Reason for revision** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Revision date** 13-Jun-2025

**Prepared By** Pfizer Global Environment, Health, and Safety

**Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.**