Erythromycin Lactobionate for Injection, USP

Safety Data Sheet (SDS)

05/2022

SECTION 1: IDENTIFICATION

1.1. (a) Product Identifier

Product Form: Powder

Product Name: Erythromycin Lactobionate for Injection, USP

Product Code: ETM

National Drug Code (NDC): 14789-116-05 (5 pack carton); 14789-116-07 (20 mL vial)

CAS Number: 114-07-8

Chemical Family: Polypeptide; lyophilized

(b) Other means of identification: None

1.2. (c) Intended Use of the Product substance/mixture: Drug Substance

1.3. (d) Name, Address, and Telephone of the Responsible Party Company

Nexus Pharmaceuticals, Inc.
400 Knightsbridge Parkway
Lincolnshire, IL
60069
USA
1-847-996-3790
www.nexuspharma.net

1.4. (e) Emergency Telephone Number, Hazardous Materials or Dangerous Goods Incident, Spill, Leak, Fire, Exposure, or Accident:

Call CHEMTREC 24 Hours: 1-800-424-9300 / 1-703-527-3887

Customer Service Team email: CHEMTREC@chemtrec.com

SECTION 2: HAZARDS IDENTIFICATION

2.1. (a) Classification of the Substance or Mixture

Hazard Class	Hazard Category
Acute Toxicity, oral	4
Acute Toxicity, dermal	4
Acute Toxicity, inhalation	4
Sensitization, skin	1, 1A, 1B
Sensitization, respiratory	1, 1A, 1B
Serious Eye Damage/ Eye Irritation	2A
Reproductive Toxicity	2
Reproductive Toxicity, effects on or via lactation	Additional category

(b) Label ElementsGHS-US Labeling

CLP/GHS Hazard Pictorial

GLP/GHS Signal Word: Danger and Warning

CLP/GHS Hazard statements:

H302: Harmful if swallowed.
H312: Harmful if contact with skin.
H317: May cause an allergic skin reaction.
H319: Cause serious eye irritation.
H332: Harmful if inhaled.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361: Suspected of damaging fertility or the unborn child.
H362: May cause harm to breast-fed children

CLP/GHS precautionary statement:

P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood

SECTION 2 CONTINUED: HAZARDS IDENTIFICATION

P260: Do not breath/dust/fume/gas/mist/vapors/spray.
P261: Avoid breathing dust/fume/gas/mist/vapors/spray.
P264: Wash face, hands, and any exposed skin thoroughly after handing.
P270: Do not eat, drink, or smoke when using this product.
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

Response Statement(s)

P330: Rinse mouth.
P301+P312: IF SWOLLOWED: Immediately call a POISON CENTER/doctor/ physician if you feel unwell.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313: If exposed or concerned: Get medical advice/attention.
P333+P313: If skin irritation or rush occurs: Get medical advice/attention.
P337+P313: If eye irritation persists: Get medical advice/attention.
P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician.
P362+P364: Take off contaminated clothing and wash it before reuse.
P302+P352+p313: If on skin: Wash with plenty of water/cleaning agents. Immediately call a POISON/CENTER/doctor/physician if you feel unwell.
P305+P351+P338: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Storage statement(s)

P405 Store locked up

Disposal Statement(s)

P501 Dispose of contents/container to an approved waste disposed plant

2.2. (c) Other hazards No data available.

2.3. Unknown Acute Toxicity (GHS-US): Not applicable.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance/Mixture: Mono-constituent substance

Chemical Name	Common Name/Synonym	% Composition or other measures	CAS No.	Impurities/Stabilizing Additives
3R*,4S*,5S*,6R*,7R*,9R*,11R*,12R*,13S*,14R*)-4-[(2,6-Dideoxy-3-C-methyl-3-O-methyl-α-L-ribo-hexopyranosyl)oxy]-14-ethyl-7,12,13-trihydro xy-3,5,7,9,11,13-hexamethyl-6-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xyl o-hexopyranosyl]oxy]oxacyclotetradecane-2,10-dione (Erythromycin A)	ERYTHROMYCIN	100%	114-07-08	N/A

Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance: N/A

SECTION 4: FIRST AID MEASURES

4.1. (a) Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.

First-aid Measures After Inhalation: Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

First-aid Measures After Skin Contact: Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

First-aid Measures After Eye Contact: Immediately flush eyes thoroughly with water for at least 15 minutes.

SECTION 4 CONTINUED: FIRST AID MEASURES

Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention.

First-aid Measures After Ingestion: Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

4.2. (b) Most important symptoms and effects, both acute and delayed Symptoms/Injuries:

Irritation of eyes and mucous membranes. Gastrointestinal disturbances.

4.3. (c) Indication of Any Immediate Medical Attention and Special Treatment Needed:

Treatment of overdose should be symptomatic and supportive. Perform gastric lavage. Administer activated charcoal as a slurry. Monitor vital signs. Monitor ECG. Monitor fluid and electrolyte status. Monitor liver enzymes. Monitor pancreatic enzyme levels. For allergic or anaphylactoid reactions, open airway and administer antihistamines, corticosteroids, and/or epinephrine. For moderate or severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against Clostridium difficile colitis. Hemodialysis is unlikely to be of benefit.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. (a) Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: A heavy water stream may spread burning liquid. CAUTION: Carbon dioxide is an asphyxiant. Lack of oxygen can be fatal.

(b) Special Hazards Arising from the Substance or Mixture: Hazardous reactions will not occur under normal conditions.

5.2. (c) Special protective equipment and precautions for fire-fighters:

Firefighting Instructions: Exercise caution when fighting any chemical fire. Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Firefighters must use full bunker gear including NIOSH-approved positive-pressure self-contained breathing apparatus to protect against potential hazardous combustion and decomposition products.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. (a) Personal Precautions, Protective Equipment and Emergency Procedures General Measures: Avoid all unnecessary exposure. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.

Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

For Non-emergency Personnel Protective Equipment: Use appropriate personal protection equipment (PPE). Refer to section 8. 2..

Emergency Procedures: Ventilate area

For Emergency Responders Protective Equipment: Equip cleanup crew with proper protection. For further information refer to section 8: "Exposure controls/personal protection".

Environmental Precautions: Prevent entry to sewers and public waters.

6.2. (b) Methods and Material for Containment and Cleaning Up Methods:

Vacuum spillage with a vacuum cleaner having a high efficiency particulate (HEPA) filter, or absorb liquid with clay absorbent, absorbent pads, or paper towels. Use plastic tools to scoop up, sweep or containerize spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water.

(c) Reference to Other Sections See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.

SECTION 7: HANDLING AND STORAGE

7.1. **(a) Precautions for Safe Handling Hygiene Measures:** Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

(b) Conditions for Safe Storage, Including Any Incompatibilities Technical Measures: Comply with applicable regulations. Protected from light and store at not more than 30°C.

(c) Incompatible Products: Not applicable

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. **(a) Exposure Limit:** No exposure limit value known.

8.2. **(b) Appropriate Engineering Controls:** Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contamination at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Body protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

8.3. **(c) Personal Protective Equipment**: Gloves. Safety glasses.

Hand Protection: Chemically compatible gloves. For handing solutions, ensure that the glove material is protective against the solvent being used. Use handing practices that minimize direct hand contact.
Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powder latex gloves should be avoided due to the risk of latex allergy.

Eye/Face Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection is preferred. Maintain eyewash facilities in the work area.

Skin and Body Protection: Avoid skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including use of apron, face shield, boots, or full body protection. A safety shower should be in the work area. Recommended protective materials include Butyl rubber and for limited contact Teflon

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection, and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Other Information: When using, do not eat, drink, or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. **Information on Basic Physical and Chemical Properties**

(a) Appearance (physical state. Color, etc.),	**:** Physical state at 20°C: Powder White and slightly yellow crystals
(b) Odor	: Odorless, bitter to taste
(c) Odor Threshold	: Not found
(d) pH	: 8.0 – 10.5
(e) Melting Point/freezing point	: 135-140° C
(f) Initial boiling point and boiling range	: Not found
(g) Flash Point	: Not found
(h) Evaporation rate	: Not found
(i) Flammability (solid, gas)	: Not found

SECTION 9 CONTINUED: PHYSICAL AND CHEMICAL PROPERTIES

(j) Upper/lower flammability or explosive limits	: Not found
(k) Vapor Pressure	: Not found
(l) Vapor Density	: Not found
(m) Relative Density	: Not found
(n) Solubility (ies)	: Slightly soluble in water and freely soluble in alcohol, soluble in methanol
(o) Partition Coefficient: N-Octanol/Water	: 3.06
(p) Auto-ignition temperature	: Not found
(q) Decomposition temperature	: Not found
(r) Viscosity	: Not found

SECTION 10: STABILITY AND REACTIVITY

10.1. **(a) Reactivity:** No reactivity hazards known.

10.2. **(b) Chemical Stability:** Stable at normal conditions.

10.3. **(c) Possibility of Hazardous Reactions:** No hazardous reaction known under conditions of normal use.

10.4. **(d) Conditions to Avoid:** Heat, flames, and sparks

10.5. **(e) Incompatible Materials:** Incompatible with strong oxidizing agents.

10.6. **(f) Hazardous Decomposition Products:** NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire condition.

10.7. **(g) Hazardous polymerization**: Will not occur

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. **Information On Toxicological Effects**

(a) Likely Route of entry: May be absorbed by inhalation, skin contact and ingestion**.**

(b) Symptoms related to the physical, chemical, and toxicological characteristics: Macrolide antibiotics: Nausea. Vomiting. Abdominal pain. Diarrhea. Taste perversion. Yellow eyes or skin. Hearing loss. Ringing in ears. Fever.

Eye contact: May cause eye irritation.

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation

Skin contact: May be harmful if absorbed through skin. May cause skin irritation.

Ingestion May be harmful if swallowed.

(c) Delayed and immediate effects and chronic effects from short- and long-term exposure:

Macrolide antibiotics: Cholestasis. Blood disorders. Ototoxicity. Superinfection. Pseudomembranous colitis. Irregular heart rate.

(d) Acute Toxicity:

Component	Type	Route	Species	Dosage
Erythromycin	LD_{50}	Oral	Rat Mouse Hamster	4600 mg/ kg 2580 mg/kg 3018 mg/kg
Erythromycin	LD_{50}	Dermal	Rabbit	No data available
Erythromycin	LD50	Inhalation	Rat	No data available

Additional Information: RTECS: KF437500.

SECTION 11 CONTINUED: TOXICOLOGICAL INFORMATION

(e) Hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA.

NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC

OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

No data available.

Carcinogenicity

No studies identified.

Human health data

See "Section 2 - Other Hazards"

SECTION 12: ECOLOGICAL INFORMATION

12.1. (a) Ecotoxicity: LC50 (Fathead Minnows): 349mg/L EC50 (Daphnia): Not found

12.2. (b) Persistence and Degradability: Not established.

12.3. (c) Bio accumulative Potential: Not established

12.4. (d) Mobility in Soil: No applicable ecological information found.

12.5. (e) Other Adverse Effects: Not applicable.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

(a) Sewage Disposal Recommendations: Do not empty into drains; dispose of this material and its container in a safe way.

(b) Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT: Not regulated for transport

(a) UN Number: Not applicable

(b) UN Proper Shipping Name: Not applicable.

(c) Transportation Hazardous Class (es): Not applicable.

(d) Packing group: Not applicable.

(**e) Environmental Hazards (e.g., Marine pollutant**): No

(f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable.

(g) Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises: Transport and intermediate store at not more than 30 °C is recommended. Not more than 40±2 ℃ & 75%±5%RH for short-term excursions (within 6 months) outside the recommended conditions.

14.2. In Accordance with IMDG: Not regulated for transport

14.3. In Accordance with IATA: Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 Regulatory Information

This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations (HPR) and the SDS contains all the information required by the HPR

International Regulatory Information: Risk Phrase(s): R42/43, R63

Safety Phrase(s): S22, S24, S36/37, S45, S51, S53

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

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

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

Refer to Nexus Pharmaceuticals, Inc prescribing information for further information at:

https://www.nexuspharma.net/products/

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