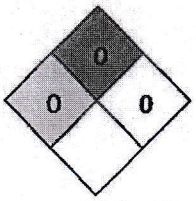
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Section1: Chemical Product and Company Identification

Product Name: Erythromycin Lactobionate
Synonyms: --
CAS No.: 3847-29-8
Molecular Weight: 1092.22
Molecular Formula: C37H67NO13.C12H22O12

NFPA Rating :



Health: ; Flammability: ; Instability: ; Specific Hazard: Nil

Contact Information:
Gland Pharma Ltd,
Plot No. 49 &50,
JN Pharmacity,
Parawada,
Visakhapatnam 531019,
Andhra Pradesh, India
Tel: +91-8924-236188/236093

Section 2: Hazards Identification

Labeling according to Regulation (EC) No 1272/2008 [CLP]:
GHS Signal Word: None
GHS Hazard Phrases:
Based on evaluation of currently available data this substance or mixture is not classifiable according to GHS.
GHS Precaution Phrases:
No phrases apply.
GHS Response Phrases:
No phrases apply.
GHS Storage and Disposal Phrases:
Please refer to Section 7 for Storage and Section 13 for Disposal information
Adverse Human Health Effects and Symptoms:
Material may be irritating to the mucous membranes and upper respiratory tract. May be harmful by inhalation, ingestion, or skin absorption. May cause eye, skin, or respiratory system irritation.
To the best of our knowledge, the toxicological properties have not been thoroughly investigated

Section 3: Composition/ Information on Ingredients

Name	CAS #	% by Weight
Erythromycin Lactobionate	3847-29-8	100

Section 4: First Aid Measures

Description of first aid measures
General Advice
If medical attention is required, show this safety data sheet to the doctor.
If Inhaled
If inhaled, move person to fresh air. If not breathing, give artificial respiration and consult a

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physician.

In Case of Skin Contact

Wash affected area with soap and water. Consult a physician if any exposure symptoms are observed.

In Case of Eye Contact

Immediately rinse eyes with plenty of water for at least 15 minutes. Consult a physician.

If Swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Do NOT induce vomiting unless advised to do so by a physician or Poison Control Center. Seek medical attention.

Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling (see section 2) and/or section 11.

Indication of any immediate medical attention and special treatment needed: no data available

Section 5: Fire and Explosion Data

Extinguishing media

Suitable extinguishing media :

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Special hazards arising from the substance or mixture :

Carbon oxides, Nitrogen oxides

Advice for firefighters :

Wear self-contained breathing apparatus for firefighting if necessary.

Further information: No data available

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal

Reference to other sections

For disposal see section 13.

Section 7: Handling and Storage

Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.

Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Keep in a dry place

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Storage conditions: Material is hygroscopic. Store at 2-8°C and protect from light.

Section 8: Exposure Controls/ Personal Protection

Control parameters

Components with workplace control parameters

Exposure controls

Appropriate engineering controls

A laboratory fume hood or other appropriate form of local exhaust ventilation should be used to avoid exposure.

Personal protective equipment

All recommendations below are advisory in nature and a risk assessment should be performed by the employer/end user prior to use of this product. The type of protective equipment must be selected based on the amount and concentration of the dangerous material being used in the workplace.

Eye/face protection

Safety goggles or face shield. All equipment should have been tested and approved under appropriate standards, such as NIOSH (US), CSA (Canada), or EN 166 (EU).

Skin protection

Gloves should be used when handling this material. Gloves are to be inspected prior to use. Contaminated gloves are to be removed using proper glove removal technique so that the outer surface of the glove does not contact bare skin. Dispose of contaminated gloves after use in compliance with good laboratory practices and local requirements.Gloves used for incidental exposures (splash protection) should be designated as "chemical resistant" by EU standard EN 374 with the resistance codes corresponding to the anticipated use of the material. Unrated gloves are not recommended.Suggested gloves: AnsellPro Sol-Vex nitrile gloves style 37-175, 15 mil thickness.

Gloves used for prolonged direct exposure (immersion) should be designated "chemical resistant" as per EN 734 with the resistance codes corresponding to the anticipated use of the material. Suggested gloves: AnsellPro Viton/Butyl gloves style 38-612, 4/8 mil thickness.
Penetration time has not been determined.

These recommendations may not apply if the material is mixed with any other chemical, or dissolved into a solution. A risk assessment must be performed to ensure the gloves will still offer acceptable protection.

Body Protection

Fire resistant (Nomex) lab coat or coveralls

Respiratory protection

Recommended respirators are NIOSH-approved N100 or CEN-approved FFP3 particulate respirators. These are to be only used as a backup to local exhaust ventilation or other

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respirators. These are to be only used as a backup to local exhaust ventilation or other engineering controls. If the respirator is the only means of protection, a full-face supplied air respirator must be used.

Section 9: Physical and Chemical Properties	
Physical state and appearance	Solid
Colour	White to off-white
Odor	No data available
Odor Threshold	No data available
pH	6.5-7.5 (2% aqueous solution)
Boiling Point	No data available
Melting Point	No data available
Evaporation Rate	No data available
Specific Gravity	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Viscosity	No data available
Water/Oil Dist. Coeff.	No data available
Solubility	No data available

Section 10: Stability and Reactivity Data

Reactivity
No data available
Chemical stability: Stable under recommended storage conditions
Possibility of hazardous reactions: no data available,
Conditions to avoid: no data available
Incompatible materials :
Strong oxidizing agents

Hazardous decomposition products

In the event of fire: See section 5.
Other decomposition products: No data available

Section 11: Toxicological Information

Information on toxicological effects
Acute toxicity:
Oral LD50: No data available. **Inhalation LC50:** No data available
Dermal LD50: No data available

Skin corrosion/irritation No data available

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Serious eye damage/eye irritation No data available

Respiratory or skin sensitization No data available

Germ cell mutagenicity No data available

Carcinogenicity: No data available

Reproductive toxicity/tetragenicity : No data available

Specific target organ toxicity - single exposure no data available

Specific target organ toxicity - repeated exposure no data available

Aspiration hazard no data available

Potential health effects and Routes of Exposure

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion	May be harmful if swallowed.
Skin	May be harmful if absorbed through skin. May cause skin irritation.
Eyes	May cause eye irritation.

Signs and Symptoms of Exposure

The most important known symptoms and effects are described in the labeling (see section 2.2) and/or section 11.To the best of our knowledge, the chemical, physical, and toxicological properties of this material have not been thoroughly investigated.

Additional Information

RTECS: Not available

Section 12: Ecological Information

Toxicity

No data available

Persistence and degradability no data available

Bioaccumulative potential no data available

Mobility in soil no data available

Results of PBT and vPvB assessment no data available

Other adverse effects No data available

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Section 13: Disposal Considerations

Waste treatment methods

Product

Product may be burned in an incinerator equipped with afterburner and scrubber. Excess and expired materials are to be offered to a licensed hazardous material disposal company. Ensure that all Federal and Local regulations regarding the disposal and destruction of this material are followed.

Section 14: Transport Information

UN number

DOT (US): N/A IATA: N/A IMDG: N/A ADR/RID: N/A

UN proper shipping name

DOT (US)/IATA: Not dangerous goods

IMDG/ARD/RID: Not dangerous goods

Transport hazard class(es)

DOT (US): N/A IATA: N/A IMDG: N/A ADR/RID: N/A

Packaging group

DOT (US): N/A IATA: N/A IMDG: N/A ADR/RID: N/A

Environmental hazards

DOT (US): None IATA: None IMDG: None ADR/RID: None

Section 15: Other Regulatory Information

This safety data sheet complies with the requirements of WHMIS (Canada), OSHA 1910.1200 (US), and EU Regulation EC No. 1907/2006 (European Union).

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

A) Canada

DSL/NDSL Status: This product is not listed on the Canadian DSL/NDSL.

B) United States

TSCA Status: This product is not listed on the US EPA TSCA.

C) European Union

ECHA Status: This product is not registered with the EU ECHA

Chemical Safety Assessment : No data available

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Section 16: Other Information

Disclaimer:

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

Prepared By: 06/01/23

Reviewed By: 06/01/2023