

**Safety Data Sheet**

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name ERYTHROMYCIN ETHYLSUCCINATE USP NON-MICRONIZED
Commercial Name Not available.
Product Use Pharmaceutical active ingredient
Restrictions On Use Not available.
Product Code 30-3116
Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: Not available.
CFR 1910.1200
Signal Word DANGER
Hazard Statement(s) May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Pictogram(s) or Symbol(s)

**Precautionary Statement(s):**

Prevention Avoid breathing dust/fume/gas/mist/vapours/spray. P280 Wear protective gloves.
Response If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Storage Not available.
Disposal Not available.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Erythromycin Ethylsuccinate USP Non-Micronized
% By Weight 100
CAS# 1264-62-6
Molecular Weight 862.06 g/mole
Chemical Formula C₄₃H₇₅N₀₁₆
Synonym(s) Erythromycin 2'-(ethyl butanedioate)

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Erythromycin Ethylsuccinate USP Non-Micronized	1264-62-6	100	N/A	N/A

Section 4: First-Aid Measures

Inhalation	Call a physician if symptoms develop or persist.
Skin Contact	Get medical attention if irritation develops and persists.
Eye Contact	Remove contact lenses, if present and easy to do. Continue rinsing.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Symptoms/Effects	
Acute	Pharmacologically active material.. Occupational exposure may cause physiological effects.
Delayed	Pharmacologically active material.. Occupational exposure may cause physiological effects.

Immediate Medical Attention

Treat symptomatically. Treatment for overdose of macrolide antibiotics may include the following: Administer activated charcoal as a slurry. This is most effective when administered within one hour of ingestion. Consider gastric lavage if it can be performed soon after ingestion, unless contraindicated. Control seizures prior to initiation and protect airway. To relieve gastric distress, administer food, milk, or antacid orally. Mild to moderate allergic reactions may be treated with antihistamines with or without inhaled beta adrenergic agonists, corticosteroids or epinephrine. Treatment of severe anaphylaxis also includes oxygen supplementation, aggressive airways management, epinephrine, ECG monitoring, and IV fluids.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable Extinguishing Media

Not available.

Products of Combustion

Not available.

Firefighters Special Equipment and Precautions

Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. Methods and materials for containment and cleaning up: Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS. Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

Handling: As a general rule, when handling USP materials, 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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Storage: Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	TWA 0.1 mg/m ³
Engineering Controls	For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

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Personal Protection

Eye/face protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. Skin protection Hand protection: Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other: Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Respiratory protection: Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene considerations: Handling practices in this SDS are recommendations for laboratory use of USP materials.

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Section 9: Physical and Chemical Properties

Appearance	White. Powder. Solid.		
Odor	Odorless		
Odor Threshold	Not available.		
Melting Point	228.2 - 230 °F (109 - 110 °C)	pH	in aqueous solution 6 - 8.5
Freezing Point	Not available.	Vapor Pressure	< 0.0000001 kPa (77 °F (25 °C))
Boiling Point/Range	Not available.	Vapor Density	Not available.
Decomposition temperature	Not available.	Viscosity	Not available.
Partition Coefficient: n-octanol/water	Not available.	Evaporation Rate	Not available.
Flash Point	Not available.	Autoignition temperature	Not available.
Flammability	Not available.	Flammability or Explosive Limits:	
		Lower	Not available.
		Upper	Not available.
Solubility(ies)	Very slightly soluble in water.		
Other	Chloroform: Freely soluble. Ethanol: Freely soluble. Methanol: Freely soluble. Chemical family Macrolide antibiotic		

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Material is stable under normal conditions.
Hazardous Polymerization	Not available.
Conditions to Avoid	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Contact with incompatible materials
Incompatible Materials	Strong oxidizing agents. Acids.
Hazardous Decomposition Products	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

RTECS	WM9800000
Acute Toxicity	Oral LD50 Mouse > 7 g/kg Oral Acute LD50 Mouse > 10 g/kg
Skin Corrosion/Irritation	Non irritant
Serious Eye Damage/Irritation	Non irritant
Respiratory or Skin Sensitization	Not available.
Germ Cell Mutagenicity	Not available
Carcinogenicity	Not available.
Reproductive Toxicity	Not available.
Routes of Entry	Not available

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Symptoms Related to Exposure

Macrolide antibiotics: Gastrointestinal disturbances. Taste perversion. Yellow eyes or skin. Hearing loss. Ringing in ears. Fever

Potential Health Effects

Not available.

Target Organ(s)

Not available.

Section 12: Ecological Information**Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and Degradability

Not available.

Bioaccumulative Potential

Not available.

Mobility in Soil

Not available.

Other Adverse Effects

Not available.

Section 13: Disposal Considerations**Waste Disposal**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Disposal of Container

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Other Considerations

Not available.

Section 14: Transport Information**DOT Classification**

DOT Not regulated as dangerous goods

Section 15: Regulatory Information**Regulations**

US federal regulations: This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200 Toxic Substances Control Act (TSCA) TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053) Not listed. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical SARA 313 (TRI reporting) Not regulated Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Contains component(s) regulated under the Safe Drinking Water Act. Safe Drinking Water Act (SDWA) US state regulations California Proposition 65 California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov

Other

Not available.

Section 16: Other Information

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Data supplied in this safety data sheet are based upon our actual knowledge. They describe only safety measures in handling of material and do not represent a warranty of the described properties. It should be remarked that the typical properties above mentioned are considered only as informative and do not constitute any specification. The receiver of our product should observe, under its responsibility, the corresponding legal regulations.