

Section 1: Identification

Common Name/Trade Name	CLARITHROMYCIN USP	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Product Synonym(s)	N/A	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, Oral (Category 4)	
Signal Word	Warning	
Hazard Statement(s)	H302	Harmful if swallowed
Pictogram(s)		
Precautionary Statement(s)	P264 P301+P312 P330 P501	Wash hands thoroughly after handling. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	N/A
Common Name	Clarithromycin
CAS Number	81103-11-9
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Remove from exposure. Remove contaminated clothing, persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen, obtain medical attention.
If Inhaled	Remove to fresh air. If breathing becomes difficult, call a physician.
In Case of Skin Contact	Flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes.
In Case of Eye Contact	Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention.
If Swallowed	Wash out mouth with water provided person is conscious.
Most Important Symptoms and Effects	Gastrointestinal disturbances.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or foam as appropriate for surrounding fire and materials. Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Special Hazards Arising From the Substance/Mixture	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.
Special PPE and/or Precautions for Firefighters	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and clothing.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	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.
Methods and Materials Used for Containment	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. Wash spill site.
Cleanup Procedures	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. Wash spill site.

Section 7: Handling and Storage

Precautions for Safe Handling	Avoid dust formation. Take precautionary measures against static discharges. Keep away from source of ignition and flame. Compatible chemical-resistant gloves. Chemical safety goggles. Mechanical exhaust required.
Conditions for Safe Storage	Preserve in tight containers. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	No biological exposure limits noted for the ingredient.
Appropriate Engineering Controls	Airborne exposure should be controlled primarily by engineering controls such as a general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant 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. Local exhaust ventilation such as laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
PPE - Eye/Face Protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area. Engineering Controls: Engineering controls such as exhaust ventilation are recommended.
PPE - Skin Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
PPE - Body Protection	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
PPE - Respiratory Protection	Use a NIOSH approved respirator, if it is determined to be necessary by industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Section 9: Physical and Chemical Properties

Appearance	White or almost white crystalline powder.
Upper/Lower Flammability or Explosive Limits	No data available
Odor	No data available
Vapor Pressure	<0.0000001kPa at 25°C
Odor Threshold	No data available
Vapor Density	No data available
pH	7.5-10.0 (0.2% suspension in water and methanol (19:1))
Relative Density	No data available
Melting Point/Freezing Point	217-225°C (decomposes)
Solubility	Practically insoluble in water, soluble in acetone and methylene chloride, slightly soluble in methanol.
Initial Boiling Point and Boiling Range	No data available
Flash Point	No data available
Evaporation Rate	No data available
Flammability (Solid, Gas)	No data available
Partition Coefficient	No data available
Auto-Ignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical Stability	Material is stable under normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	None known.
Incompatible Materials	Oxidizing agents.
Hazardous Decomposition Products	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	LD50, Oral Rat: 1270 mg/kg. Harmful if swallowed
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	No data available
Serious Eye Damage/Irritation	No data available
Respiratory or Skin Sensitization	No data available
Germ Cell Mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity IARC	Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Carcinogenicity ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
Carcinogenicity NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
Carcinogenicity OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
Reproductive Toxicity	Adequate and well-controlled studies in humans have not been done; however, in animal studies large doses of clarithromycin have caused adverse effects on the fetus. Studies in rat showed an increased incidence of cardiovascular abnormalities. In mice, high doses of clarithromycin increased the incidence of cleft palate. Monkeys given doses equivalent to the maximum human recommended dose had fetal growth retardation, and rabbits given doses equivalent to 17 times less than the maximum recommended human daily dose had an increased incidence of fetal loss.
Specific Target Organ Toxicity - Single Exposure	Due to lack of data the classification is not possible
Specific Target Organ Toxicity - Repeated Exposure	Due to lack of data the classification is not possible
Aspiration Hazard	No data available

Section 12: Ecological Information

Toxicity	No data available
Persistence and Degradability	No data available
Bio-accumulative Potential	No data available
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Incinerate in an approved facility. Observe all federal state and local environmental regulations.
Waste Treatment Methods Packaging	No data available.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	N/A

Section 15: Regulatory Information

CERCLA/SARA Hazardous Substances -Not applicable. One or more components are not listed on TSCA. California proposition 65: developmental toxicity.

Section 16: Other Information

Additional Information	N/A
Prepared By	Lisa Russell
Revision Date	01/14/2019 11:01

Disclaimer

Letco Medical, LLC believes that the above information is 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. If the product is used as a component in another product, this information may not be applicable. NO WARRANTY OF FITNESS FOR ANY PARTICULAR PURPOSE, WARRANTY OF MERCHANTABILITY OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, IS MADE CONCERNING THE INFORMATION PROVIDED ABOVE. Letco Medical shall not be held liable for any loss or damage resulting from handling, storage, use or from contact with the above product.