


Section 1: Identification

Common Name/Trade Name	AZITHROMYCIN DIHYDRATE	
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)	CP-62993, XZ405, Zithromax, N-Methyl-11-aza-10-deoxo-10-dihydroerythromycin A; 9-Deoxo-9amethyl-9a-aza-homoerythromycin A; 9-deoxo-9methyl-9aaza-9-homoerythromycin A	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Skin Sensitization, Category 1, Respiratory Sensitization, Category 1	
Signal Word	Danger	
Hazard Statement(s)	H317 H334	May cause an allergic skin reaction May cause allergy or asthma symptoms or breathing difficulties if inhaled
Pictogram(s)		
Precautionary Statement(s)	P261 P280 P333+P313 P342+P311	Avoid breathing dust/fume/gas/mist/vapours/spray. Wear protective gloves/protective clothing/eye protection/face protection. If skin irritation or a rash occurs Get medical advice/attention. If experiencing respiratory symptoms Call a POISON CENTER or doctor/physician.
Hazards Not Otherwise Classified	No data available	
Ingredient(s) with Unknown Toxicity	No data Available	

Section 3: Composition/Information on Ingredients

Chemical Name	1-Oxa-6-azacyclopentadecan-15-one, 13-((2,6-dideoxy-3-O-methylalpha-L-ribo-exopyranosyl)oxy)-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11((3,4,6-trideoxy-3-(dimethylamino)-beta-D-xylohexopyranosyl)oxy)-...
Common Name	Azithromycin dihydrate
CAS Number	117772-70-0
Impurities and/or Stabilizing Additives	No data available

Section 4: First Aid Measures

General Advice	Consult a physician. Show this safety data sheet to the doctor in attendance.
If Inhaled	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.
In Case of Skin Contact	Wash with soap and water. Cover the irritated skin with an emollient. Get medical attention if irritation develops. Cold water may be used.
In Case of Eye Contact	Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used. Get medical attention if irritation occurs.
If Swallowed	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Loosen tight clothing such as a collar, tie, belt or waistband. Get medical attention if symptoms appear.
Most Important Symptoms and Effects	No data available.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	For small fires, use dry chemical powder. For large fires, use water spray, fog or foam. Do not use water jet.
Special Hazards Arising From the Substance/Mixture	As with most organic solids, fire is possible at elevated temperatures. Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard. May be combustible at high temperature. Products of combustion: These products are carbon oxides (CO, CO ₂), nitrogen oxides (NO, NO ₂ ...). Slightly flammable to flammable in presence of heat. Non-flammable in presence of shocks. Slightly explosive in presence of open flames and sparks. Non-explosive in presence of shocks.
Special PPE and/or Precautions for Firefighters	Wear self contained breathing apparatus for fire fighting if necessary.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Splash goggles, Full suit. Dust respirator. Boots. Gloves. A self contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.
Methods and Materials Used for Containment	Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements. Large spill: Use shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.
Cleanup Procedures	Small spill: Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements. Large spill: Use shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

Section 7: Handling and Storage

Precautions for Safe Handling	Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk, evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe dust. If ingested, seek medical advice immediately and show the container or the label. Keep away from incompatibles such as oxidizing agents.
Conditions for Safe Storage	Keep container tightly closed. Keep container in a cool, well-ventilated area.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	No data available. Exposure limits: Not available.
Appropriate Engineering Controls	Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.
PPE - 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.
PPE - Skin Protection	Gloves: Chemically compatible. For handling solutions, ensure that the gloves 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 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	Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested approved under appropriate government standards such as NIOSH (US)

Section 9: Physical and Chemical Properties

Appearance	Physical state: solid. Form: crystalline. Color: white
Upper/Lower Flammability or Explosive Limits	Not available
Odor	Odorless
Vapor Pressure	Not applicable
Odor Threshold	Not available
Vapor Density	Not applicable
pH	Not available
Relative Density	No data available
Melting Point/Freezing Point	133°C (271.4°F) - 135°C
Solubility	Partially soluble in cold water
Initial Boiling Point and Boiling Range	Not available
Flash Point	Not available
Evaporation Rate	Not available
Flammability (Solid, Gas)	No data available
Partition Coefficient	Not available
Auto-Ignition Temperature	Not available
Decomposition Temperature	No data available
Viscosity	No data available

Section 10: Stability and Reactivity

Reactivity	No data available
Chemical Stability	The product is stable.
Possibility of Hazardous Reactions	No data available
Conditions to Avoid	Heat, incompatible materials.
Incompatible Materials	Oxidizing agents.
Hazardous Decomposition Products	Polymerization: Will not occur.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Acute oral toxicity (LD50): >2000 mg/kg [Rat].
Acute Toxicity - Inhalation	No data available
Acute Toxicity - Dermal	No data available
Acute Toxicity - Eye	No data available
Skin Corrosion/Irritation	May cause skin irritation.
Serious Eye Damage/Irritation	May cause eye irritation.
Respiratory or Skin Sensitization	May affect respiration (respiratory depression).
Germ Cell Mutagenicity	No data available
Carcinogenicity IARC	No data available
Carcinogenicity ACGIH	No data available
Carcinogenicity NTP	No data available
Carcinogenicity OSHA	No data available
Reproductive Toxicity	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

Section 12: Ecological Information

Toxicity	Not available
Persistence and Degradability	No data available
Bio-accumulative Potential	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise. The product itself and its products of degradation are not toxic.
Mobility in Soil	No data available
Other Adverse Effects	No data available

Section 13: Disposal Considerations

Waste Treatment Methods Product	Waste must be disposed of in accordance with federal, state and local environmental control regulations.
Waste Treatment Methods Packaging	Waste must be disposed of in accordance with federal, state and local environmental control regulations.
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	No data available.

Section 15: Regulatory Information

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

Section 16: Other Information

Additional Information	Further Toxicological information: Potential health effects: Inhalation: Toxic if inhaled. May cause respiratory tract irritation. Ingestion: Toxic if swallowed. May cause gastrointestinal tract irritation with abdominal pain, diarrhea, loose stools, dyspepsia, flatulence, nausea, constipation, taste perversion, anorexia, oral moniliasis, mucositis, melena and vomiting. May cause adverse reproductive effects based on animal test data. May affect behavior/central nervous system (somolence, ataxia, dizziness, vertigo, agitation, tiredness, nervousness, insomnia), urinary system/kidneys (dark urine caused by hematuria; acute failure, nephritis), blood (leukopenia, neutropenia, decreased platelet count), cardiovascular system (palpitations, chest pain). Other symptoms may include vaginitis, urticaria, pruritus. Chronic Potential Health Effects: Possible allergic reaction/hypersensitization if material is inhaled, ingested or in contact with skin. Symptoms may include skin rash itching, hives, anaphylaxis, angioedema, photosensitivity. Ingestion: Prolonged or repeated ingestion may affect the liver (cholestatic jaundice causing yellowing of eyes and skin).
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