


Section 1: Identification

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| 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

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| 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

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| 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

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| 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

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| 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

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| 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

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| 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

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| 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

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| 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

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| 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

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| 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

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| 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

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| 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

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| 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

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| 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, kidney 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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