

**Section 1: Identification**
**Product Name** Azithromycin USP Dihydrate

**Commercial Name** Not available.

**Product Use** Not available

**Restrictions On Use** Not available

**Product Code** 30-4173

**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:** According to the classification provided by companies to ECHA in CLP notifications this substance may cause an allergic skin reaction and may cause allergy or asthma symptoms or breathing difficulties if inhaled.

**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):**

<b>Prevention</b>	P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves/protective clothing/eye protection/face protection. P284 Wear respiratory protection.
<b>Response</b>	P302 + P352 IF ON SKIN: Wash with plenty of water. P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P333 + P313 If skin irritation or rash occurs: Get medical advice/attention. P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. P362 Take off contaminated clothing and wash before reuse.
<b>Storage</b>	Not available
<b>Disposal</b>	P501 Dispose of contents/container to an approved waste disposal plant.

**Section 3: Composition/Information on Ingredients**
**Substance/Mixture** Substance

**Components** Azithromycin USP Dih

**% By Weight** 100

**CAS#** 117772-70-0

**Molecular Weight** 733.93

**Chemical Formula** C38H72N2O2\*2H2O

**Synonym(s)** (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6- dideoxy -3 -C- methyl -3 -O- methyl -a-L- ribo - hexopyranosyl )oxy] -2- ethyl- 3,4,10 -tri hyd roxy- 3,5,6,8,10,12,14 -he ptam ethyl -11- [[3,4,6- trideoxy -3- (dimethylamino) -o -D -xylo- hexopyranosyl] oxy ]- 1- oxa -6- azacyclopentadecan -15 -one dihydrate

**Mixtures**

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Azithromycin USP Dih	117772-70-0	100	N/A	N/A

**Section 4: First-Aid Measures**

<b>Inhalation</b>	If inhaled, Remove exposed person from source of exposure to fresh air. If not breathing, clear airway and start cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.
<b>Skin Contact</b>	Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
<b>Eye Contact</b>	In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Contact lenses should be removed. Obtain medical attention if pain, blinking or redness persist.
<b>Ingestion</b>	If swallowed, wash out mouth with water provided person is conscious. Call a physician.
<b>Symptoms/Effects</b>	
<b>Acute</b>	Not available.
<b>Delayed</b>	Delayed adverse effects possible.

**Immediate Medical Attention**

In case of reactions described in hazards identification or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.

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

Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder. Appropriate foam.

**Unsuitable Extinguishing Media**

Water may be ineffective in firefighting due to low solubility.

**Products of Combustion**

Emits toxic fumes under fire conditions. Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

**Firefighters Special Equipment and Precautions**

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

**Section 6: Accidental Release Measures**

Personal precautions, protective equipment and emergency procedures: Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection. Avoid any direct contact with the product. Evacuate unnecessary personnel. Environmental precautions: Keeping away from drains, surface and ground water. Methods and material for containment and cleaning up: Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean with the help of detergents. Collect all waste in suitable and labeled containers and dispose according to local legislation. Wash the non-recoverable remainder with: Sodium hypochlorite solution.

**Section 7: Handling and Storage**

Precautions for safe handling: Do not get in eyes, on skin or on clothing. Do not breathe dust. Keep container closed. Use only with adequate ventilation. Handle in accordance with good industrial hygiene and safety procedures. Wash hands before eating, drinking, smoking. Remove contaminated clothing and clean before re-use. Conditions for safe storage, including any incompatibilities: Preserve in an airtight container and store at not more than 30°C. Keep away from all heat sources, including direct sunlight.

**Section 8: Exposure Controls/Personal Protection**

<b>Exposure Limits</b>	Not available.
<b>Engineering Controls</b>	Mechanical exhaust required. Provide mechanical ventilation for confined spaces.

**Safety Data Sheet**

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

**Personal Protection**

Eye protection: Wear chemical safety goggles and face shield. Have eye-wash stations available where eye contact can occur. Skin protection: Avoid skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including use of apron, face shield, boots or full body protection. A safety shower should be located in the work area. Recommended protective materials include: Butyl rubber and for limited contact Teflon. Respiratory protection: Wear approved mask. In case of insufficient ventilation, wear suitable respiratory equipment such as NIOSH(US) or CEN(EU), Where risk assessment shows air-purifying respirators are appropriate use a dust mask type N95(US) or type P1(EN143) respirator. Hand protection: Wear suitable gloves resistant to chemical penetration. Industrial hygiene: Provide local exhaust or general room ventilation.

**Section 9: Physical and Chemical Properties**

<b>Appearance</b>	White or almost white powder. Bitter in taste		
<b>Odor</b>	Odorless		
<b>Odor Threshold</b>	Not available.		
<b>Melting Point</b>	Around 120-130°C	<b>pH</b>	9.0-11.0
<b>Freezing Point</b>	Not available.	<b>Vapor Pressure</b>	Not available.
<b>Boiling Point/Range</b>	Not available.	<b>Vapor Density</b>	Not available.
<b>Decomposition temperature</b>	Not available.	<b>Viscosity</b>	Not available.
<b>Partition Coefficient: n-octanol/water</b>	Not available.	<b>Evaporation Rate</b>	Not available.
<b>Flash Point</b>	Not available.	<b>Autoignition temperature</b>	Not available.
<b>Flammability</b>	Not applicable	<b>Flammability or Explosive Limits:</b>	
		<b>Lower</b>	Not applicable
		<b>Upper</b>	Not applicable
<b>Solubility(ies)</b>	Practically insoluble in water, freely soluble in anhydrous ethanol, acetone and methylene chloride.		
<b>Other</b>	Not available.		

**Section 10: Stability and Reactivity**

<b>Reactivity</b>	Not available
<b>Chemical Stability</b>	Stable under normal conditions.
<b>Hazardous Polymerization</b>	No hazardous reaction known under conditions of normal use.
<b>Conditions to Avoid</b>	Not available
<b>Incompatible Materials</b>	Incompatible with strong oxidizers.
<b>Hazardous Decomposition Products</b>	Nitrogen oxides. Carbon dioxide. Carbon monoxide. When heated to decomposition, emits dangerous fumes.

**Section 11: Toxicological Information**

<b>RTECS</b>	RN 6960000				
<b>Acute Toxicity</b>					
Oral LD50 [Rat]	>2000 mg/kg	Oral LD50 [Mouse]	3000 mg/kg	Dermal LD50 [Rabbit]	n/f
[Rat]	n/f				Inhalation LC50
<b>Skin Corrosion/Irritation</b>					
May cause skin irritation. May be harmful if absorbed through the skin.					
<b>Serious Eye Damage/Irritation</b>					
May cause eye irritation.					
<b>Respiratory or Skin Sensitization</b>					
Material may be irritating to mucous membranes and upper respiratory tract. May be harmful if inhaled.					
<b>Germ Cell Mutagenicity</b>					
Not available.					
<b>Carcinogenicity</b>					
Not available.					
<b>Reproductive Toxicity</b>					
Not available.					
<b>Routes of Entry</b>					
Inhalation. Ingestion. Eue. Skin.					

**Symptoms Related to Exposure**

This material may cause allergic respiratory reaction and allergic skin reaction, may cause blood disorders and/or aggravate pre-existing blood disorders. Gastrointestinal disorders

**Potential Health Effects**

Not available

**Target Organ(s)**

Not available.

**Section 12: Ecological Information****Ecotoxicity**

Not available

**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**

Disposal Procedure: Dispose of waste in a safe manner in accordance with all applicable Federal, State and local laws.

Waste from residues/unused products: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

**Disposal of Container**

Dispose of as unused product. Observe all federal state and local environmental regulations.

**Other Considerations**

Not available

**Section 14: Transport Information****DOT Classification**

UN- Number ADR /RID: IMDG: IATA: UN proper shipping name ADR /RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods Transport hazard class(es) ADR /RID: IMDG: IATA: Packaging group ADR /RID: IMDG: IATA: Environmental hazards ADR /RID: No IMDG Marine pollutant: No IATA: No Special precautions for users

**Section 15: Regulatory Information****Regulations**

International Regulatory Information: Risk Phrase(s): R42/43 Safety Phrase(s): S22, S24/25, S36/37/39 Labeling according to CLP/GHS: Symbol(s): Warning, Danger Hazard Statement(s): H317, H334 Safety Precaution(s): P261, p272, P280, P284, P321, P302+P352, P304+P340, P333+P313, P342+P311, P362+P364, P501

**Other**

Not available

**Section 16: Other Information**



## Safety Data Sheet

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Azithromycin USP Dihydrate

30-4173

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Further information The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide for technically qualified personnel. 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. Alembic Pharmaceuticals Ltd. extends no warranties, makes no representations and assumes no responsibility as to the accuracy, completeness or suitability of this data for any third party use & shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.