


**SECTION 1: PRODUCT IDENTIFICATION**

<b>PRODUCT NAME</b>	<b>AZITHROMYCIN, USP (Dihydrate)</b>
<b>PRODUCT CODE</b>	<b>2246</b>
<b>SUPPLIER</b>	<b>MEDISCA Inc.</b> Tel.: 1.800.932.1039   Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 <b>MEDISCA Pharmaceutique Inc.</b> Tel.: 1.800.665.6334   Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 <b>MEDISCA Australia PTY LTD</b> Tel.: 1.300.786.392   Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
<b>EMERGENCY PHONE</b>	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
<b>RECOMMENDED USES</b>	Manufacturing and Compounding
<b>RESTRICTIONS ON USE</b>	Not applicable

**SECTION 2: HAZARDS IDENTIFICATION**

<b>GHS CLASSIFICATION</b>	Acute Toxicity - Oral (Category 5) Eye Irritation (Category 2B) Sensitization - Respiratory (Category 1) Sensitization - Skin (Category 1) Acute Aquatic Toxicity (Category 3)
<b>PICTOGRAM</b>	
<b>SIGNAL WORD</b>	Danger
<b>HAZARD STATEMENT(S)</b>	May be harmful if swallowed. Causes eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Harmful to aquatic life.
<b>ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS</b>	Not Applicable.

**PRECAUTIONARY STATEMENT(S)**
**Prevention**

Avoid breathing dust, fume, gas, mist, vapors, spray.  
 In case of inadequate ventilation wear respiratory protection.  
 Contaminated work clothing must not be allowed out of the workplace.  
 Wear protective gloves.  
 Wear eye and face protection.  
 Wash hands thoroughly after handling. Do not touch eyes.  
 Avoid release to the environment.

**Response**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical help.  
 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms, get medical help immediately call a poison center or medical professional.  
 IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

**Storage**

Not applicable

**Disposal**

Dispose of contents and/or container in accordance with local regulations.

**HMIS CLASSIFICATION**
**Health Hazard**

2

**Flammability**

0

**Reactivity**

0

**Personal Protection**

G

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**
**CHEMICAL NAME**

1-Oxa-6-azacyclopentadecan-15-one, 13-  
 [(2,6-dideoxy-3-C-methyl-3-O-methyl- $\alpha$ -L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)- $\beta$ -D-xylo-hexopyranosyl]oxy]-, dihydrate, [2R(2R\*,3S\*,4R\*,5R\*,8R\*,10R\*,11R\*,12S\*,13S\*,14R\*)]

**BOTANICAL NAME**

Not applicable

**SYNONYM**

Not applicable

**CHEMICAL FORMULA**

C<sub>38</sub>H<sub>72</sub>N<sub>2</sub>O<sub>12</sub> · 2H<sub>2</sub>O

**CHEMICAL FAMILY**

Azalide; macrolide

**CAS NUMBER**

117772-70-0

**ALTERNATE CAS NUMBER**

Not applicable

**MOLECULAR WEIGHT**

785.0184

**COMPOSITION**

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
AZITHROMYCIN	117772-70-0	641-134-5	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

**SECTION 4: FIRST-AID MEASURES**
**IN CASE OF EYE CONTACT**

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

**IN CASE OF SKIN CONTACT**

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

**IF SWALLOWED**

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

**IF INHALED**

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

**MEDICAL ATTENTION AND SPECIAL TREATMENT**

Get emergency medical help.

**SYMPTOMS CAUSED BY EXPOSURE**

Not expected to present a significant hazard under anticipated conditions of normal use.

**SECTION 5: FIREFIGHTING MEASURES****SPECIFIC HAZARDS ARISING FROM THE CHEMICAL**

Not applicable

**FLAMMABLE PROPERTIES**

May be combustible at high temperature

**HAZARDOUS COMBUSTION PRODUCTS**

Under fire conditions, hazardous fumes will be present.

**SUITABLE & UNSUITABLE EXTINGUISHING MEDIA**

**Small fire:** dry chemical, CO<sub>2</sub> or water spray. **Large fire:** dry chemical, CO<sub>2</sub>, alcohol resistant foam or water spray. Do not get water inside containers.

**PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS**

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

**SECTION 6: ACCIDENTAL RELEASE MEASURES****PERSONAL PRECAUTIONS**

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

**METHODS & MATERIAL FOR CONTAINMENT**

On land, sweep or shovel into suitable containers. Minimize generation of dust.

**CLEANUP PROCEDURE**

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

**REFERENCE TO OTHER SECTIONS**

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

**SECTION 7: HANDLING AND STORAGE****PRECAUTIONS FOR SAFE HANDLING**

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**CONDITIONS FOR SAFE STORAGE**

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

**STORAGE CONDITIONS**

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40 °C are acceptable.

**SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION**
**Chemical Name: AZITHROMYCIN CAS #: 117772-70-0**

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m <sup>3</sup>	ppm	mg/m <sup>3</sup>				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

**EXPOSURE GUIDELINES**

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m<sup>3</sup>.

**PERSONAL PROTECTIVE EQUIPMENT**

**Eyes:** Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

**SPECIFIC ENGINEERING CONTROLS**

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

**BIOLOGICAL MONITORING**

Not available

**CONTROL BANDING**

Not available

**NOTES**

 USP: ELV: Industrial TWA: 0.5 mg/m<sup>3</sup>
**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**
**PHYSICAL STATE**

Solid

**DESCRIPTION**

White or almost white powder.

**SOLUBILITY**

Freely soluble in anhydrous ethanol and in methylene chloride; practically insoluble in water.

**ODOR**

Odorless

**FLAMMABILITY**

May be combustibile at high temperature

**AUTO-IGNITION TEMPERATURE**

Not available

**BOILING POINT**

Not available

**DECOMPOSITION TEMPERATURE**

Not available

**EVAPORATION RATE**

Not available

**EXPLOSIVE LIMIT**

Not available

**FLASH POINT**

Not available

<b>log P (OCTANOL-WATER)</b>	4.02	<b>LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)</b>	Not available	<b>MELTING/FREEZING POINT</b>	(133-135)°C, (271.4-275)°F
<b>PARTICLE CHARACTERISTICS</b>	Not available	<b>OXIDIZING PROPERTY</b>	Not available	<b>pH</b>	9.0 - 11.0 (0.2% H <sub>2</sub> O, methanol, 1:1)
<b>RELATIVE DENSITY (WATER = 1)</b>	Not available	<b>SPECIFIC GRAVITY</b>	Not available	<b>UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)</b>	Not available
<b>VAPOR DENSITY (AIR = 1)</b>	Not available	<b>VAPOR PRESSURE</b>	Not available	<b>VISCOSITY</b>	Not available

The physical data presented above are typical values and should not be construed as a specification.

## SECTION 10: STABILITY AND REACTIVITY

<b>REACTIVITY</b>	Not established
<b>CHEMICAL STABILITY</b>	Stable under recommended storage conditions
<b>INCOMPATIBLE MATERIALS</b>	Strong oxidants
<b>HAZARDOUS DECOMPOSITION PRODUCTS</b>	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
<b>HAZARDOUS POLYMERIZATION</b>	Will not occur
<b>POSSIBILITY OF HAZARDOUS REACTION</b>	Not established
<b>CONDITIONS TO AVOID</b>	Moisture, sunlight and extreme temperatures

## SECTION 11: TOXICOLOGICAL INFORMATION

<b>ACUTE TOXICITY</b>	Oral: Rat: LD50: (mg/kg): > 2000 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
<b>SKIN CORROSION/IRRITATION</b>	Due to lack of data, the classification is not possible.
<b>SERIOUS EYE DAMAGE/EYE IRRITATION</b>	Causes eye irritation: pH 9.0 - 11.0
<b>RESPIRATORY SENSITIZATION</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>SKIN SENSITIZATION</b>	May cause an allergic skin reaction.
<b>GERM CELL MUTAGENICITY</b>	Based on available data, the classification criteria are not met. Bone marrow clastogenic assay. Result: Negative. Species: Mouse Lymphocyte clastogenic assay. Result: Negative. Species: Human Lymphoma assay. Result: Negative. Species: Mouse Salmonella Ames assay. Result: Negative.
<b>CARCINOGENICITY</b>	<b>OSHA</b> AZITHROMYCIN is not listed. <b>NTP</b> AZITHROMYCIN is not listed.

<b>ADDITIONAL CARCINOGENICITY INFORMATION</b>	<b>IARC</b> AZITHROMYCIN is not evaluated.
<b>REPRODUCTIVE TOXICITY</b>	<b>California Proposition 65</b> This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm. Due to lack of data the classification is not possible.
<b>SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE</b>	Based on available data, the classification criteria are not met. Mouse: 0 - 200 mg/kg/day Reproductivity, No evidence of harm to the fetus, despite maternal toxicity. Result: Negative Rat: 0 - 200 mg/kg/day Reproductivity, No evidence of harm to the fetus, despite maternal toxicity. Result: Negative Human: Reproductivity, No increased incidence of birth defects in children born to mothers who used azithromycin therapeutically during pregnancy. Result: Negative Due to lack of data the classification is not possible.
<b>SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE</b>	Due to lack of data the classification is not possible.
<b>ASPIRATION HAZARDS</b>	Based on available data, the classification criteria are not met.
<b>SIGNS AND SYMPTOMS OF EXPOSURE</b>	<b>ROUTES OF EXPOSURE:</b> Inhalation, skin, eyes, ingestion <b>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:</b> Not available <b>DELAYED HEALTH EFFECT FROM EXPOSURE:</b> Liver impairment. Superinfections.  Symptoms related to the physical, chemical, and toxicological characteristics Abdominal pain. Diarrhea. Gas. Nausea. Vomiting. Taste changes. Headache. Dizziness. Tiredness. Loss of balance. Hearing problems. Ringing in ears. Irregular heartbeat. Dark urine.  Cross sensitivity: Persons sensitive to erythromycin or any ketolide or macrolide antibiotic may be sensitive to this material also.  Medical conditions aggravated by exposure: Impaired liver function. Myasthenia gravis. Prolonged QT intervals.
<b>POTENTIAL HEALTH EFFECTS</b>	<b>Inhalation</b> May be harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. <b>Ingestion</b> May be harmful if swallowed. <b>Skin</b> May be harmful if absorbed through skin. May cause skin irritation. May cause an allergic skin reaction. <b>Eyes</b> Causes eye irritation.

## SECTION 12: ECOLOGICAL INFORMATION

<b>ECOTOXICITY</b>	EC50: 48 Hr: Crustacea: Daphnia magna: (mg/L): 75 LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available
<b>PERSISTENCE AND DEGRADABILITY</b>	Not available
<b>BIOACCUMULATIVE POTENTIAL</b>	LogPow: 4.02
<b>MOBILITY IN SOIL</b>	Practically insoluble in water: 7.090 mg/L (25°C) Henry's Law Constant: 5.30E-29atm-m <sup>3</sup> /mole (25°C)
<b>OTHER ADVERSE EFFECTS</b>	Not available

This product is not intended to be released into the environment

## SECTION 13: DISPOSAL CONSIDERATIONS

### DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

## SECTION 14: TRANSPORT INFORMATION

### UN PROPER SHIPPING NAME

Not dangerous good

### UN NUMBER

Not applicable

### CLASS

Not applicable

### PACKING GROUP

Not applicable

### AUSTRALIA

#### HAZCHEM

Not applicable

### EU

#### TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not Listed

### ENVIRONMENTAL HAZARDS

Not available

### SPECIAL SHIPPING INFORMATION

Not applicable

## SECTION 15: REGULATORY INFORMATION

### UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
AZITHROMYCIN 117772-70-0	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

### AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
AZITHROMYCIN 117772-70-0	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

### EU REGULATIONS

