Section 1 - Identification

(a)	**Product Identifier:**	Azithromycin for Injection, USP (500 mg/vial)
(b)	**Product Code:**	70860-100
	Common/Trade Name:	Azithromycin Monohydrate
	Chemical Name:	*(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)*-13-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-*L*-*ribo*-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-hepta-methyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-*D*-*xylo*-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.
	Chemical Family:	Antibiotic / Antifungal
(c)	**Product Use:**	Pharmaceutical, Injectable
	Product Type:	Regulated Prescription Drug
	Container Information:	Vial
(d)	**Distributor:**	Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
(e)	**Emergency Telephone:**	855-273-0154

Section 2 - Hazards Identification

(a) Classification: **OSHA Classification:** Non-hazardous in accordance with international standards for workplace safety

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	**(c) Description of Hazards:**
Signal Word:	- Not Available

Hazard Statements

- Non hazardous in accordance with international standards for workplace safety
- Dust may cause irritation. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

(d) Unknown Acute Toxicity N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-dideoxy-3-*C*-methyl-3-*O*-methyl-α-*L*-*ribo*-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-hepta-methyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-*D*-*xylo*-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one.	Azithromycin (as azithromycin monohydrate), USP	500.0 mg/unit	83905-01-5	N/A
2-Hydroxy-1,2,3-propanetricarboxylic acid monohydrate	Citric Acid monohydrate, USP	420.67 mg per unit	5949-29-1	N/A
Sodium Hydroxide	Sodium Hydroxide	q.s.	1310-73-2	N/A

Section 4 - First Aid Measures

Eye Exposure: Flush eyes with large volumes of water for 15 minutes or more. Seek medical attention if irritation or signs of exposure are noted.

Skin Exposure: Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Seek medical attention.

Ingestion: 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.

Injection: In cases of accidental injection, wash and disinfect area, seek medical attention.

Inhalation: Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.

Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures

(a)	**Extinguishing Media**	Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
(b)	**Hazardous Combustion Products:**	During thermal decomposition, it may be possible to generate irritating vapors and /or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx)
(c)	**Special Protective Equipment / Precautions:**	Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard. Wear self-containing breathing apparatus and protective clothing.

Section 6 - Accidental Release Measures

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.

Release to Air: If aerosolized, reduce exposures by ventilating area. Clean up immediately.

Release to Water: Refer to local and regional water authority requirements.

Section 7 - Handling and Storage

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Storage Conditions: Store at 20° to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Follow instructions provided in packaging.

When diluted according to the instruction (1.0 mg/mL to 2.0 mg/mL), Azithromycin for injection is stable for 24 hours at or below room temperature (30°C or 86°F), or for 7 days if stored under refrigeration (5°C or 41°F).

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Azithromycin monohydrate	OSHA ACGIH -----	TLV PEL STEL	NE NE NE
Citric Acid monohydrate	OSHA ACGIH -----	PEL TLV STEL	NE NE NE

(b) Engineering Controls

Ventilation: Handle product in a well ventilated area.

(c) Individual Protection Measures

Respiratory Protection:	With satisfactory ventilation, respiratory protection is usually not required.
Eye Protection:	Safety glasses.
Skin Protection:	Disposable garments if direct skin contact is anticipated.
Other Protective Equipment:	Protective Latex or Nitrile gloves.
Additional Exposure Precautions:	Wash hands following use. No eating, drinking or smoking when handling this product.

Section 9 - Physical and Chemical Properties

(a)	**Appearance**	White to off-white lyophilized powder or cake.
(b)	**Odor**	Odorless
(c)	**Odor Threshold**	None
(d)	**pH**	6.4 – 6.8
(e)	**Melting Point:**	Not available
(f)	**Initial Boiling Point:**	Not available

(g)	**Flash Point**	Not available
(h)	**Evaporation Rate:**	Not available
(i)	**Flammability**	Not available
(j)	**Upper Lower Flammability or Explosion Limits**	Not available
(k)	**Vapor Pressure:**	Not available
(l)	**Vapor Density:**	Not available
(m)	**Relative Density**	Not available
(n)	**Solubility(ies)**	Soluble in water; freely soluble in dehydrated alcohol and in dichloromethane
(o)	**Partition Coefficient: n-octanol/water**	0.402 (Log Pow/Log Kow)
(p)	**Auto-ignition Temperature**	Not available
(q)	**Decomposition Temperature**	Not available
(r)	**Viscosity**	Not available

Section 10 - Stability and Reactivity

(a)	**Reactivity**	Not available
(b)	**Chemical Stability**	Stable at normal temperature and pressures
(c)	**Possibility of Hazardous Reactions**	Hazardous polymerization will not occur
(d)	**Conditions to Avoid**	Excess heat; incompatible materials
(e)	**Incompatible Materials**	Reactive with oxidizing agents
(f)	**Hazardous Decomposition Products**	During thermal decomposition, it may be possible to generate irritating vapors and /or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx)

Section 11 - Toxicological Information

(a)	**Likely Routes of Exposure**	Inhalation, eye/skin contact or ingestion.

(b)	**Symptoms related to the physical, chemical and toxicological characteristics**	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Most of the adverse reactions from therapeutic doses were mild to moderate in severity and were reversible upon discontinuation of the drug. Adverse events reported include: diarrhea/loose stools, nausea, abdominal pain, vomiting, pain at the injection site, and local inflammation. Occupational exposure has not been fully investigated.
(c)	**Delayed and immediate effects and also chronic effects from short and long term exposure**	Possible allergic reaction/hypersensitization if material is inhaled, ingested or in contact with skin. Symptoms may include skin rash itching, hives, anaphylaxis, angioedema, and photosensitivity. DELAYED EFFECTS: For individuals who experienced serious allergic reactions (angiodema, anaphylaxis, Stevens-Johnson, toxic epidermal necrolysis) despite successful symptomatic treatment of serious allergic reactions, when symptomatic therapy was discontinued, the allergic symptoms recurred soon thereafter in some individuals without further azithromycin exposure. These patients required prolonged period of observation and symptomatic treatment. PREGNANCY CATEGORY B: There were no adequate and well-controlled studies in pregnant women. However, in animal studies, no evidence of harm to the fetus due to azithromycin was found.

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Azithromycin	LD_{50}	Oral	Mouse (M)	3000 mg/kg
Azithromycin	LD_{50}	Oral	Mouse (P)	4000 mg/kg
Azithromycin	LD_{50}	Oral	Rat (M)	>200 mg/kg
Azithromycin	LD_{50}	Oral	Rat (F)	>2000 mg/kg
Citric Acid	LD_{50}	Oral	Rat	3000 mg/kg
Citric Acid	LD_{50}	Oral	Mouse	5040 mg/kg
Citric Acid	LD_{50}	Intravenous	Mouse	42 mg/kg
Citric Acid	LD_{50}	Intravenous	Rabbit	330 mg/kg
Sodium Hydroxide	LDLo	Oral	Rabbit	500 mg/kg

(e) Hazardous Chemical Listings

NTP: Not Listed IARC: Not Listed OSHA: Not Listed

Section 12 - Ecological Information

(a)	**Ecotoxicity**	Not determined for product. LC50(48hr, flow through) = 189 mg/l in freshwater fish for sodium hydroxide LC50(24hr, static) = 125-160 mg/l in freshwater fish for sodium hydroxide LC50(48hr, static) = 125 mg/l in freshwater fish for sodium hydroxide LC50(96hr static) = 45.4 – 125 mg/l in freshwater fish for sodium hydroxide EC(lethality) = 100 - 156 mg/l in Daphnia for sodium hydroxide LC50(96hr, static) = 444-760 mg/l and 1516 mg/l in freshwater fish for citric acid LC50(48hr, static) = 2600 mg/l in freshwater fish for citric acid. EC50(72hr) ~ 120 mg/l in Daphnia magna for citric acid EC3(7 day) = 640 mg/l in Scenedesmus quadricauda (algae) for citric acid. EC50 > 10,000 mg/l in Pseudomonas putida (bacteria) for citric acid

(b)	**Persistence and degradability**	Not Available
(c)	**Bioaccumulative potential**	Not Available
(d)	**Mobility in soil**	Not Available
(e)	**Other Adverse Effects**	Not Available

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

(a)	**UN Number**	Not Available
(b)	**UN Proper Shipping Name**	Not Available
(c)	**Transport Hazard Class(es)**	Not Available
(d)	**Packing Group**	Not Available
(e)	**Environmental Hazards**	Not Available
(f)	**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)**	Not Available
(g)	**Special Precautions**	Not Available

DOT: Not Regulated
ICAO/IATA: Not Regulated
IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:
TSCA - Not on this list
CERCLA - Not on this list
SARA 302 - Not on this list
SARA 313 - Not on this list

Section 16 - Other Information

As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY
OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a subs titute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division
10 N. Martingale Road, Suite 230
Schaumburg, IL 60173
847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit

MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS001 **Revision:** 01

Title: Azithromycin for Injection, USP (500 mg/vial)

All dates and times are in Eastern Standard Time.

SDS001

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	CORPORATE QA MANAGER	24 Jan 2017, 03:33:27 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
Tom Moutvic (TMOUTVIC)	VP of Regulatory Affairs	25 Jan 2017, 01:52:13 PM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	25 Jan 2017, 02:07:30 PM	Approved