	Sagent Pharmaceuticals, Inc.				
	Azithromycin for Injection, USP			Material Safety Data Sheet (MSDS)	
	Issue Date: October 01, 2008	MSDS No.: MSDS 012	Version No.: 1.0	Form Number: R-SOP-009-F001	Page: 1 of 9

Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600

Emergency Telephone: 866-625-1618

Product Identifier: Azithromycin for Injection, USP (500 mg/vial)
Product Code: NDC 25021-112-10
Common/Trade Name: Azithromycin Monohydrate
Chemical Name: (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-dideoxy-3-Cmethyl-3-O-methyl- α -L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)- β -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one
Chemical Family: Antibiotics / Antifungals
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vials


Section 2 - Composition / Information on Ingredients

Ingredient	mg/vial	OSHA PEL	ACGGIH TLV	Other Limits Recommended	CAS No.
Azithromycin	512	None	None	None	83905-01-5
Anhydrous citric acid	414	None	None	None	77-92-9
Sodium hydroxide	q.s.	None	None	None	1310-73-2
Nitrogen	q.s.	None	None	None	7727-37-9

Section 3 - Hazards Identification

Primary Physical and Health Hazards: 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.

Routes of Entry: Inhalation, eye/skin contact or ingestion.

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Signs & Symptoms of Exposure: 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.

Chemical Listed as Carcinogen: **NTP: No IARC: No OSHA: No**

Medical Conditions Generally Aggravated by Exposure: Individuals with a known hypersensitivity to azithromycin, erythromycin, or any other macrolide antibiotic.

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.

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Section 5 - Fire Fighting Measures


Flash Point	Not Applicable
Autoignition Temperature:	Not Applicable
Flammable Limits in Air	Lower %: Not Applicable Upper %: Not Applicable
Flammable Limits:	Not Applicable
Extinguishing Media	Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
Special Fire Fighting Procedures:	Wear self-containing breathing apparatus and protective clothing.
Unusual Fire/Explosion Hazards:	Fine dust dispersed in air in sufficient concentrations, and in the presences of an ignition source is a potential dust explosion hazard.

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.
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Waste Disposal Method: Not available.

Storage Conditions: Store the white to off-white lyophilized cake at 20° to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].

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

Respiratory Protection: With satisfactory ventilation, respiratory protection is usually not required.

Eye Protection: Safety glasses.

Ventilation: Handle product in a well ventilated area.


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.

Exposure Limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Azithromycin monohydrate	OSHA	TLV	NE
	ACGIH	PEL	NE
	-----	STEL	NE
Anhydrous citric acid	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE


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Section 9 - Physical and Chemical Properties

Physical State:	Powder	Specific Gravity:	Not Available
Appearance and Odor:	White crystalline, odorless	Evaporation Rate:	Not Available
Boiling Point:	Not Available	Solubility in Water:	Soluble
Vapor Pressure:	Not Available	pH:	Not available
Vapor Density:	Not Available	Molecular Weight	749.00

Section 10 - Stability and Reactivity

Stability:	Stable at normal temperature and pressures.
Incompatibility (Materials to avoid):	Reactive with oxidizing agents.
Hazardous Decomposition:	Not available.
Hazardous Polymerization:	Will not occur.
Conditions to Avoid:	Excess heat, incompatible materials.

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Section 11 - Toxicological Information

Signs & Symptoms of Exposure & Overexposure:

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DELAYED EFFECTS:


For individuals who experienced serious allergic reactions (angioedema, 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.

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

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Section 12 - Ecological Information

Information is currently not available on the environmental impact of Azithromycin. Handle in a manner to prevent spills or releases to the environment.

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

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent 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 issuance, 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 MATERIAL 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 substitute 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.

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

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
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
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
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
NIOSH	National Institute for Occupational Safety and Health
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
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)