



MATERIAL SAFETY DATA SHEET

Product Name: Azithromycin for Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

Emergency Telephone CHEMTREC: North America:: 800-424-9300; International: 1-703-527-3887
Hospira, Inc., Non-emergency 224 212-2055

Product Name Azithromycin for Injection

Synonyms (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-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)- β -D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one monohydrate.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Azithromycin Monohydrate
Chemical Formula C₃₈H₇₂N₂O₁₂ • H₂O

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Azithromycin Monohydrate	47	121479-24-4	NA
Citric Acid	36	77-92-9	GE7350000
Sodium Hydroxide	17	1310-73-2	WB4900000

3. HAZARD INFORMATION

Emergency Overview Azithromycin for Injection contains lyophilized azithromycin monohydrate, a macrolide antibiotic with actions and indications similar to erythromycin. It is used to treat respiratory-tract infections, skin and soft-tissue infections, and uncomplicated genital infections. In the workplace, the powdered product should be considered potentially irritating to the skin and respiratory tract, and possibly corrosive to the eyes. Based on clinical use, possible target organs include the skin, eyes, gastrointestinal system, cardiovascular system and liver.

Occupational Exposure Potential Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact.

Signs and Symptoms None known from occupational exposure. Some macrolides are irritating to the eyes. In clinical use, adverse effects may include abdominal pain and cramps, nausea, vomiting, and diarrhea. Liver dysfunction has been reported occasionally. Macrolides have been associated with QT prolongation and ventricular arrhythmias, including ventricular tachycardia and torsades de pointes. Reversible high frequency hearing loss has also been reported with some macrolides in patients with renal insufficiency. Allergic reactions (mostly rashes, pruritus, and urticaria; infrequently anaphylactoid/respiratory) have been clinically evident in a small number of treated patients. Prolonged therapy can result in overgrowth of non-susceptible bacteria/fungi.

Medical Conditions Aggravated by Exposure Pre-existing hypersensitivity to macrolide antibiotics; pre-existing gastrointestinal, cardiovascular, or liver ailments.

Carcinogen Lists: **IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed

4. FIRST AID MEASURES

Eye Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability	None anticipated from this product. Powder may be combustible at high temperatures.
Fire & Explosion Hazard	None anticipated from this product. Avoid the creation of dusty environments.
Extinguishing Media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect powder using techniques that minimize the creation of airborne dust. If spill occurs after reconstitution, absorb any liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
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7. HANDLING AND STORAGE

Handling	No special handling required under conditions of normal product use.
Storage	No special storage required for hazard control. For product protection, follow USP controlled room temperature storage recommendations noted on the product case label, the primary container label, or the product insert.
Special Precautions	No special precautions are required for hazard controls. Employees with known allergies to macrolide antibiotics should consult a health and/or safety professional prior to working with open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits			
	OSHA-PEL	ACGIH-TLV	Hospira EEL	Other Limits
Azithromycin Monohydrate	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established	Not Established
Citric Acid	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established	Not Established
Sodium Hydroxide	8 hr TWA: 2 mg/m ³	8 hr TWA: 2 mg/m ³ , Ceiling	8 hr TWA: Not Established	Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
 EEL: Employee Exposure Limit.
 TWA: 8-hour Time Weighted Average.
 STEL: 15-minute Short Term Exposure Limit.

- Respiratory Protection** Respiratory protection is normally not needed during intended product use. However, if the generation of dusts is likely and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 filter or better) is recommended. Personnel who wear respirators should be fit tested and approved for respirator use as required.
- Skin Protection** If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
- Eye Protection** Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
- Engineering Controls** Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	A white crystalline powder
Odor	NA
Odor Threshold:	NA
pH:	The pH of a 0.2% solution in a mixture of methyl alcohol and water (1:1) is between 9.0 and 11.0.
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Evaporation Rate	NA
Specific Gravity	NA
Solubility	Soluble in water; freely soluble in dehydrated alcohol and in dichloromethane.
Log Partition coefficient: n-octanol/water:	4.02
Auto-ignition temperature	NA
Decomposition temperature	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined
Chemical Stability	Stable under standard use and storage conditions
Hazardous Reactions	Not determined
Conditions to avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Azithromycin Monohydrate (117772-70-0)	100	LD50	Oral	>2000 >3000	mg/kg mg/kg	Rat Mouse
Citric Acid	100	LD50	Oral	3000 5040	mg/kg mg/kg	Rat Mouse
Citric Acid	100	LD50	Intravenous	42 330	mg/kg mg/kg	Mouse Rabbit
Sodium Hydroxide	100	LDLo	Oral	500	mg/kg	Rabbit

LD50: Dosage that produces 50% mortality.

Aspiration Hazard	None anticipated from normal handling of the intact product.
Dermal Irritation/Corrosion	None anticipated from normal handling of the intact product. However, inadvertent contact with this product formulation may be irritating to the skin. Sodium hydroxide produced severe skin irritation in a study in rabbits. Citric acid produced mild irritation in a study in rabbits.
Ocular Irritation/Corrosion	None anticipated from normal handling of the intact product. However, inadvertent contact of this product formulation with eyes may produce irritation, redness and pain. Sodium hydroxide produced severe eye irritation in a study in rabbits. Citric acid also produced severe eye irritation in a study in rabbits.
Dermal or Respiratory Sensitization	None anticipated from normal handling of the intact product. Serious allergic reactions, including angioedema, anaphylaxis and dermatologic reactions including Steven Johnson Syndrome and toxic epidermal necrolysis have been reported rarely in patients on azithromycin therapy. Allergic reactions occur in a small percentage of the population given therapeutic doses of macrolide antibiotics, estimated to be <3%. It has also been indicated that allergy to one macrolide antibiotic does not necessarily mean allergy to others.
Reproductive Effects	No evidence of impaired fertility due to azithromycin was found in animal studies. Reproduction studies have been performed in rats and mice at doses up to moderately maternally toxic dose concentrations (i.e., 200 mg/kg/day by the oral route). These doses, based on a mg/m2 basis, are estimated to be 4 and 2 times, respectively, the human daily dose of 500 mg by the oral route. In the animal studies, no evidence of harm to the fetus due to azithromycin was found

11. TOXICOLOGICAL INFORMATION: continued

Mutagenicity	Azithromycin was not mutagenic in standard laboratory tests: mouse lymphoma assay, human lymphocyte clastogenic assay, and mouse bone marrow clastogenic assay.
Carcinogenicity	Long-term studies in animals to evaluate carcinogenic potential of azithromycin have not been conducted.
Target Organ Effects	Based on clinical use, possible target organs include the possible target organs include the skin, eyes, gastrointestinal system, cardiovascular system and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	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
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

13. DISPOSAL CONSIDERATIONS:

Waste Disposal	All waste materials must be properly characterized by the waste generator. Further, disposal of all pharmaceuticals should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

DOT STATUS: Not Regulated
Proper shipping name: NA
Hazard class: NA
UN number: NA
Packing group: NA
Reportable quantity: NA

ICAO/IATA STATUS Not regulated
Proper shipping name: NA
Hazard class: NA
UN number: NA
Packing group: NA
Reportable quantity: NA

IMDG STATUS Not regulated
Proper shipping name: NA
Hazard class: NA
UN number: NA
Packing group: NA
Reportable quantity: NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION



TSCA Status This product is exempt.
CERCLA Status Sodium Hydroxide - Listed
SARA 302 Status Not listed
SARA 313 Status Not listed
RCRA Status Not listed
PROP 65 (Calif.) Not listed

Notes:
TSCA, Toxic Substance Control Act;
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act;
SARA, Superfund Amendments and Reauthorization Act;
RCRA, US EPA, Resource Conservation and Recovery Act;
Prop 65, California Proposition 65

U.S. OSHA Classification Possible Irritant (to skin)
Possible Corrosive (to eyes)
Target Organ Toxin

15. REGULATORY INFORMATION: continued

***GHS Classification** *Where medicinal products are not exempt, the recommended GHS workplace classification is as follows:

Hazard Class	Acute Oral Toxicity	Eye Irritation	Target Organ Toxicity
Hazard Category	5	1	2
Hazard Symbol	NA		
Signal Word	Warning	Danger	Warning
Hazard Statement	May be harmful if swallowed	Causes serious eye damage	May cause damage to the gastrointestinal system, cardiovascular system, and liver through prolonged or repeated exposure.


Prevention: Avoid breathing dust/vapors/spray.
 In case of inadequate ventilation wear respiratory protection as specified by the manufacturer/supplier or the competent authority.
 Wear protective gloves as specified by the manufacturer/supplier or the competent authority.
 Wear eye/face protection as specified by the manufacturer/supplier or the competent authority.

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 attention.
 If skin irritation occurs, get medical advice/attention.

Get medical attention if you feel unwell.

EU Classifications*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substances azithromycin monohydrate.

Classification(s):	Symbol:	Indication of Danger
Irritant		Xi

EU Risk Phrases: R36/37/38 - Irritating to eyes, respiratory system and skin

EU Safety Phrases: S22: Do not breathe dust
 S23: Do not breathe vapor or spray
 S25: Avoid contact with eyes
 S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
 S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD ₅₀	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Global Occupational Toxicology
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