

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Azithromycin for Injection, USP**
Manufacturer Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: January 08, 2009
SDS Revision Date: February 13, 2024

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word:

DANGER.

GHS Class:

Serious Eye Damage. category 1.
 Skin corrosion. category 1.
 Respiratory sensitisation. category 1.
 Skin Sensitization. category 1.
 Reproductive toxicity. Effects on or via lactation.

Hazard Statements:

Causes serious eye damage.
 Causes severe skin burns and eye damage.
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 May cause an allergic skin reaction.
 May cause harm to breast-fed children.

Precautionary Statements:

Obtain special instructions before use.
 Do not breathe dust/fume/gas/mist/vapours/spray.
 Avoid breathing dust/fume/gas/mist/vapours/spray.
 Avoid contact during pregnancy and while nursing.
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Contaminated work clothing should not be allowed out of the workplace.
 Wear protective gloves/protective clothing/eye protection/face protection.
 In case of inadequate ventilation wear respiratory protection.
 IF SWALLOWED: Rinse mouth. Do not induce vomiting.
 IF ON SKIN: Wash with plenty of water.
 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 IF exposed or concerned: Get medical advice/attention.
 Immediately call a POISON CENTER or doctor/physician.
 Specific treatment (see ... on this label).
 If skin irritation or rash occurs: Get medical advice/attention.
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
 Take off contaminated clothing and wash it before reuse.
 Wash contaminated clothing before reuse.
 Store locked up.
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview:

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.

Route of Exposure:

Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye:

Contact with eyes may cause irritation.

Signs/Symptoms:

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.

Aggravation of Pre-Existing Conditions:

Individuals with a known hypersensitivity to azithromycin, erythromycin, or any macrolide antibiotic.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CA#	Ingredient Percent	EC Num.
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SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature].
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling dust, vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.

Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Lyophilized powder.
Color:	White to off-white.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Very soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not established.
Molecular Formula:	Mixture
Molecular Weight:	749.0
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Chronic 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.
Teratogenicity:	Pregnancy Category B: There are 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.
<u>Azithromycin :</u>	
RTECS Number:	RN6960000
Ingestion:	Oral - Rat LD50: >2 gm/kg [Behavioral - Somnolence (general depressed activity) Lungs, Thorax, or Respiration - Respiratory depression Gastrointestinal - Nausea or vomiting] Oral - Mouse LD50: 3 gm/kg [Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Respiratory depression Gastrointestinal - Nausea or vomiting]
Other Toxicological Information:	Intraperitoneal. - Rat LDLo: 900 mg/kg [Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression Gastrointestinal - nausea or vomiting] Intraperitoneal. - Mouse LDLo: 400 mg/kg [Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression Gastrointestinal - nausea or vomiting] Intraperitoneal. - Mouse TDLo: 150 mg/kg [Lungs, Thorax, or Respiration - other changes Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation]
<u>Citric Acid, Anhydrous :</u>	
RTECS Number:	GE7350000
Eye:	Eye - Rabbit Standard Draize test.: 750 ug/24H [severe]
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Ingestion:	Oral - Rat LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 5040 mg/kg [Lungs, Thorax, or Respiration - Other changes Musculoskeletal - Other changes] Oral - Mouse LD50: 7280 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse LD50: 42 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands]
Intravenous. - Rabbit LD50: 330 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands]
Subcutaneous - Rat LD50: 5500 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes]
Subcutaneous - Mouse LD50: 2700 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes]
Intraperitoneal. - Rat LD50: 290 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 903 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD16: 197 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD: 382 mg/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.
Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.
DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Citric Acid, Anhydrous :

TSCA Inventory Status: Listed
EINECS Number: 201-069-1
Canada DSL: Listed
Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.409(80)

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 3
HMIS Fire Hazard: 0
HMIS Reactivity: 0
HMIS Personal Protection: C

SDS Creation Date: January 08, 2009
SDS Revision Date: February 13, 2024
SDS Revision Notes: Overall SDS review - no changes to formulation. Added USP to the product name. Added HMIS ratings for Health, Flammability, Reactivity, and Personal Protective Equipment (PPE).

Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

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