


## 1. Identification

<b>Product identifier</b>	<b>Azithromycin Identity</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1046067	
<b>Recommended use</b>	Specified quality tests and assay use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
<b>Telephone</b>	RS Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Note</b>	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.	
<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Sensitization, respiratory	Category 1
	Sensitization, skin	Category 1
<b>OSHA hazard(s)</b>	Not classified.	
<b>Label elements</b>		
		
<b>Signal word</b>	Danger	
<b>Hazard statement</b>	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
<b>Precautionary statement</b>		
<b>Prevention</b>	Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. Avoid breathing dust. In case of inadequate ventilation wear respiratory protection.	
<b>Response</b>	If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.	
<b>Storage</b>	Not available.	
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.	
<b>Hazard(s) not otherwise classified (HNOC)</b>	Not classified.	
<b>Environmental hazards</b>	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3

## Supplemental information

**Hazard statement** Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

## Precautionary statement

### Prevention

Avoid release to the environment.

### Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

## 3. Composition/information on ingredients

### Mixture

#### Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Azithromycin		83905-01-5	88.8
Related Impurities		No Data	11.2

## 4. First-aid measures

### Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

### Skin contact

Wash off with soap and plenty of water. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs: Get medical advice/attention.

### Eye contact

Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists.

### Ingestion

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

### Most important symptoms/effects, acute and delayed

May cause allergic skin reaction. May cause allergic respiratory reaction. Gastrointestinal disturbances.

### Indication of immediate medical attention and special treatment needed

Treatment of overdose should be symptomatic and supportive and may include the following: Perform gastric lavage soon after ingestion (within one hour). Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first. Administer activated charcoal as a slurry. For gastrointestinal discomfort, administer food, milk, or an antacid. For mild pseudomembranous colitis, treatment is generally not necessary. For moderate to severe cases, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis. Azithromycin is not dialyzable [Meditext; PDR; Drugdex]

### General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

## 5. Fire-fighting measures

### Suitable extinguishing media

Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO<sub>2</sub>.

### Unsuitable extinguishing media

None known.

### Specific hazards arising from the chemical

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

### Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

### Fire-fighting equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

### Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

### Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

## 7. Handling and storage

### Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Combustible dust clouds may be created where operations produce fine material (dust).

Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.

### Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Biological limit values

No biological exposure limits noted for the ingredient(s).

### Exposure guidelines

No exposure standards allocated.

### Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

### Individual protection measures, such as personal protective equipment

#### Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

#### Skin protection

##### Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

##### Other

For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

#### Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

#### Thermal hazards

Not available.

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical and chemical properties

### Appearance

White to off-white powder.

#### Physical state

Solid.

#### Form

Powder.

### Odor

Not available.

### Odor threshold

Not available.

### pH

Not available.

### Initial boiling point and boiling range

Not available.

### Flash point

Not available.

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not applicable.

### Upper/lower flammability or explosive limits

#### Flammability limit - lower (%)

Not available.

#### Flammability limit - upper (%)

Not available.

#### Explosive limit - lower (%)

Not available.

#### Explosive limit - upper (%)

Not available.

### Vapor density

Not available.

### Relative density

Not available.

<b>Solubility in water</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	No reactivity hazards known.
<b>Chemical stability</b>	Stable at normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	None known.
<b>Incompatible materials</b>	Oxidizing agents.
<b>Hazardous decomposition products</b>	NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Due to lack of data the classification is not possible.
<b>Inhalation</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
<b>Skin contact</b>	May cause an allergic skin reaction.
<b>Eye contact</b>	Due to lack of data the classification is not possible.

**Symptoms related to the physical, chemical, and toxicological characteristics** Component: Abdominal pain. Diarrhea. Gas. Nausea. Vomiting. Taste changes. Headache. Dizziness. Tiredness. Loss of balance. Hearing problems. Ringing in ears. Irregular heartbeat. Dark urine.

**Delayed and immediate effects of exposure** Component: Liver impairment. Superinfections.

**Cross sensitivity** Persons sensitive to erythromycin or any ketolide or macrolide antibiotic may be sensitive to this material also.

**Medical conditions aggravated by exposure** Component: Impaired liver function. Myasthenia gravis. Prolonged QT intervals.

### Acute toxicity

Components	Species	Test Results
Azithromycin (CAS 83905-01-5)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Mouse	3000 mg/kg
	Rat	> 2000 mg/kg

**Skin corrosion/irritation** Due to lack of data the classification is not possible.

**Serious eye damage/eye irritation** Due to lack of data the classification is not possible.

**Respiratory sensitization** May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Skin sensitization** May cause an allergic skin reaction.

**Germ cell mutagenicity** Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

### Mutagenicity

Azithromycin	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.
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**Carcinogenicity** Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

**Reproductive toxicity** Due to lack of data the classification is not possible.

**Reproductivity**  
Azithromycin Retrospective reproductivity and development studies  
Result: No increased incidence of birth defects in children born to mothers who used azithromycin therapeutically during pregnancy.  
Species: Human

**Specific target organ toxicity - single exposure** Due to lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure** Due to lack of data the classification is not possible.

**Aspiration hazard** Based on available data, the classification criteria are not met.

## 12. Ecological information

**Ecotoxicity** Contains a substance which causes risk of hazardous effects to the environment.

Components	Species	Test Results
Azithromycin (CAS 83905-01-5)		
Crustacea	EC50 Daphnia magna	75 mg/l, 48 hours

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** Not available.

**Mobility in soil** Not available.

**Other adverse effects** Not available.

## 13. Disposal considerations

**Disposal instructions** Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

**Local disposal regulations** Not available.

**Hazardous waste code** Not available.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as a hazardous material by DOT.

### IATA

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** No information available.

## 15. Regulatory information

**US federal regulations** CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - Yes  
Delayed Hazard - No  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance** No

**SARA 311/312 Hazardous chemical** No

### Other federal regulations

**Safe Drinking Water Act (SDWA)** Not regulated.

**Food and Drug Administration (FDA)**

Not regulated.

**US state regulations**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

**16. Other information, including date of preparation or last revision**

<b>Issue date</b>	03-24-2015
<b>Version #</b>	01
<b>Further information</b>	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
<b>Disclaimer</b>	USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.