

Azithromycin for Injection

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Identification

Product name : Azithromycin for Injection -- NDC 55150-174-10

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics
6 Wheelling Road
Dayton, NJ 08810
T 609-642-1136

1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Acute Tox. 4 (Oral) H302
Skin Corr. 1A H314
Eye Dam. 1 H318

Full text of H-phrases: see section 16

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H302 - Harmful if swallowed
H314 - Causes severe skin burns and eye damage

Precautionary statements (GHS-US) :

P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P301+P312 - If swallowed: Call a poison center/doctor if you feel unwell
P301+P330+P331 - If swallowed: rinse mouth. Do NOT induce vomiting
P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a poison center/doctor
P330 - Rinse mouth
P363 - Wash contaminated clothing before reuse
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

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3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Azithromycin Monohydrate	(CAS No) 121470-24-4	50	Acute Tox. 4 (Oral), H302
Citric acid	(CAS No) 77-92-9	38.5	Not classified
Sodium hydroxide	(CAS No) 1310-73-2	11.4	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen and monitor closely. Get medical attention immediately.
First-aid measures after skin contact	: Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact	: Immediately flush with plenty of water for at least 15 minutes occasionally lifting upper and lower eyelids. If easy to do, remove contact lenses. Get medical attention if symptoms persist.
First-aid measures after ingestion	: DO NOT induce vomiting. If victim is fully conscious, give a cupful of water. Never give anything by mouth to an unconscious person. If vomiting occurs, keep head lower than the hips to help prevent aspiration. Call a physician or poison control center immediately.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation	: Dust may cause irritation of the respiratory system.
Symptoms/injuries after skin contact	: None anticipated from normal handling of the product. Accidental contact with product formulation may cause irritation. Prolonged contact may cause skin burns
Symptoms/injuries after eye contact	: None anticipated from normal handling of the product. Accidental contact with product formulation may cause serious irritation, redness and pain.
Symptoms/injuries after ingestion	: Ingestion may cause gastrointestinal harm.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
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5.3. Advice for firefighters

Protection during firefighting	: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: No special measures required.
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6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment	: Stop the flow of material, if this is without risk.
Methods for cleaning up	: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dust formation.

6.4. Reference to other sections

No additional information available

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Wear protective clothing as described in Section 8 of this safety data sheet. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Use only with adequate ventilation. Wash thoroughly after handling. Minimize dust generation and accumulation.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at controlled room temperature at 20–25 °C (68-77°F). Store away from incompatible materials

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : Use neoprene or rubber gloves.
Eye protection : In case of dust production: protective goggles.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : Wear NIOSH approved respirator when handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Powder.
Color : white
Odor : Odorless.
Odor threshold : No data available
pH : No data available
Melting point : No data available
Freezing point : No data available
Boiling point : No data available
Flash point : No data available
Relative evaporation rate (butyl acetate=1) : No data available
Flammability (solid, gas) : No data available
Explosion limits : No data available
Explosive properties : No data available
Oxidizing properties : No data available
Vapor pressure : No data available
Relative density : No data available
Relative vapor density at 20 °C : No data available
Solubility : Soluble
Log Pow : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : No data available
Viscosity, kinematic : No data available
Viscosity, dynamic : No data available

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9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

None

10.5. Incompatible materials

Not determined

10.6. Hazardous decomposition products

Not determined

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

Azithromycin for Injection	
ATE US (oral)	1000.000 mg/kg body weight
Citric acid (77-92-9)	
LD50 oral rat	3 g/kg
ATE US (oral)	3000.000 mg/kg
Sodium hydroxide (1310-73-2)	
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350.000 mg/kg
Azithromycin Monohydrate (121470-24-4)	
ATE US (oral)	500.000 mg/kg body weight

Skin corrosion/irritation : Causes severe skin burns and eye damage.

Serious eye damage/irritation : Causes serious eye damage.

Respiratory or skin sensitization : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Citric acid (77-92-9)	
LC50 fish 1	1516 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
Sodium hydroxide (1310-73-2)	
LC50 fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Citric acid (77-92-9)

Log Pow	-1.72 (at 20 °C)
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12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on the global warming : No known ecological damage caused by this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not a dangerous good as defined in transport regulations

SECTION 15: Regulatory information

15.1. US Federal regulations

Citric acid (77-92-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium hydroxide (1310-73-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State regulations

Sodium hydroxide (1310-73-2)

U.S. - Massachusetts - Right To Know List
U.S. - Minnesota - Hazardous Substance List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product