



浙江国邦药业有限公司

ZHEJIANG GUOBANG PHARMACEUTICAL CO., LTD.

地址：中国浙江省杭州湾上虞工业区内纬五路6号 邮编：312369 传真：086-575-82735575 电话：086-575-82739355

No.6, Wei Wu Road, Hangzhou Gulf Shangyu Industrial Zone, Zhejiang, P.R.China (312369) Fax: 086-575-82735575 Tel: 086-575-82739355

MATERIAL SAFETY DATA SHEET

SECTION 1-PRODUCT AND COMPANY IDENTIFICATION

Manufacturer's Name: Zhejiang Guobang Pharmaceutical Co., Ltd.

Address: No.6, Weiwu Road, Hangzhou GulfShangyu Industrial Zone, Zhejiang, China

Emergency Tele No.: 0086-575-86128944, 86126559

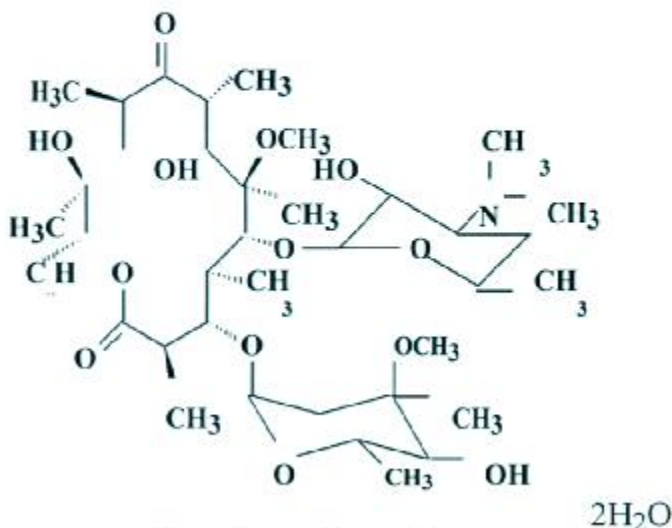
Product Name: Azithromycin

Chemical Name:

(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 dihydrate.

CAS# 117772-70-0

Structure:



Appearance: white or almost white powder

SECTION 2 -HAZARD INFORMATION

Adverse effects: Mild nausea, vomiting, diarrhea, constipation, or stomach pain;
Dizziness, tired feeling, or headache; vaginal itching or discharge; Mild itching or skin rash.

Overdose Effects: Symptoms of overdose include nausea, vomiting, diarrhea, and prostration.
Treatment is supportive and symptomatic.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation. **Chronic:**
Possible hypersensitization and suprainfection.

Medical Conditions Aggravated by Exposure:

Hypersensitivity to the material and severely impaired kidney or liver function.

Cross Sensitivity: Persons sensitive to erythromycin or other macrolide antibiotics may be sensitive to this material also.

Target Organs: n/f



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For additional information on toxicity, see section 11.

SECTION 3-

COMPOSITION/INFORMATION ON INGREDIENTS

Azithromycin

$C_{38}H_{72}N_2O_{12} \cdot 2H_2O$ N-Methyl-11-aza-10-deoxo-10-dihydroerythromycinA dihydrate

Common Name:

Formula:

Synonym:

Chemical name:

(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 dihydrate.

CAS: 117772-70-0

RTECS Number: n/f

Chemical Family: Macrolide antibiotic

Therapeutic Category: Antibacterial

Composition: The material contains 96.0%~ 102.0% of clarithromycin on the anhydrous basis

SECTION 4-FIRST AID MEASURES

Inhalation:

May cause irritation. Remove to fresh air.

Eye:

May cause irritation. Flush with copious quantities of water.

Skin:

May cause irritation. Flush with copious quantities of water.

Ingestion:

May cause irritation. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract.

General First Aid procedures:

Remove from exposure. Remove contaminated clothing, persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

SECTION 5-FIREFIGHTING MEASURES

Extinguisher Media:

Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Fire and explosion Hazards:

This material is assumed to be combustible. AS with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

Firefighting Procedures:

As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and clothing.

SECTION 6-ACCIDENTAL RELEASE MEASURES

Spill Response:

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately-labelled container for disposal. Wash spill site



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SECTION 7-HANDLING AND STORAGE

Handling:

As a general rule, when handling this material, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

Storage: Store in tight container as defined in labeling insert. This material should be handled and stored per label instructions to ensure product integrity.

SECTION 8-EXPOSURE CONTROL /PERSONAL PROTECTION

Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection:

Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

SECTION 9-PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the active substance Lot provided.

| | |
|-----------------------------|---|
| Appearance and Odor: | White to off-white powder, odorless. |
| Odor Threshold: | n/f |
| PH: | 9.0-11.0 (suspension in water and methanol (2:1)) |
| Melting Range: | 133-135°C (decomposes) |
| Boiling Point: | n/f |
| Flash Point: | n/f |
| Autoignition Temperature: | n/f |
| Evaporation Rate: | n/f |
| Upper Flammability Limited: | n/f |
| Lower Flammability Limited: | n/f |
| Vapor Pressure: | n/f |
| Vapor Density: | n/f |
| Specific Gravity: | n/f |
| Solubility in Water: | Practically insoluble |
| Fat Solubility: | n/f |
| Other Solubility: | Soluble in anhydrous ethanol and methylene chloride; slightly soluble in water. |
| Partition Coefficient: | n-octanol/water: n/f |
| Percent Volatile: | n/ |
| Reactivity in Water: | n/f |
| Explosive Properties: | n/f |
| Oxidizing Properties: | n/f |
| Formula: | C ₃₈ H ₇₂ N ₂ O ₁₂ ·2H ₂ O |
| Molecular Weight: | 785.02 |



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周志全

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SECTION 10- STABILITY AND REACTIVITY

Conditions to avoid: n/f
Incompatibilities: oxidizing agents
Decomposition products: when heated to decomposition material emits toxic fumes of NO_x. Emits toxic fumes under fire conditions.
Stable? Yes
Hazardous Polymerization? No

SECTION 11- TOXICOLOGICAL INFORMATION

Oral rat: LD50: 2000mg/kg
Oral mouse: n/f
Other toxicity data: n/f
Irritancy data: n/f
Corrosivity: n/f
Sensitization data: n/f
Listed as a carcinogen by: NTP: No IARC: No OSHA: No
Other carcinogenicity data: no
Mutagenicity data: negative in mutagenicity assays.

Reproductive and developmental effects:

Phospholipidosis (intracellular phospholipid accumulation) has been observed in some tissues of mice, rats, and dogs given multiple doses of azithromycin. It has been demonstrated in numerous organ systems (e.g., eye, dorsal root ganglia, liver, gallbladder, kidney, spleen, and/or pancreas) in dogs treated with azithromycin at doses which, expressed on the basis of mg/m², are approximately one-sixth the recommended adult dose, and in rats treated at doses approximately one-fourth the recommended adult dose. This effect has been shown to be reversible after cessation of azithromycin treatment. Based on the pharmacokinetic data, phospholipidosis has been seen in the rat (50 mg/kg/day dose) at the observed maximal plasma concentration of 1.3 µg/mL (1.6 times the observed C_{max} of 0.821 µg/mL at the adult dose of 2.0 g). Similarly, it has been shown in the dog (10 mg/kg/day dose) at the observed maximal serum concentration of 1.0 µg/mL (1.2 times the observed C_{max} of 0.821 µg/mL at the adult dose of 2.0 g). The significance of the finding for animals and for humans is unknown.

SECTION 12- ECOLOGICAL INFORMATION

Ecological information: n/f

SECTION 13- DISPOSAL CONSIDERATIONS

DISPOSAL: Dispose of waste in accordance with all applicable federal, state and local laws.

SECTION 14- TRANSPORT INFORMATION

Shipping name: n/f
Class: n/f
Un number: n/f
Packing group: n/f
Additional transport information: n/f



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MSDS / Azithromycin

Zhejiang Guobang Pharmaceutical Co., Ltd.

SECTION 15- REGULATORY INFORMATION



Symbol(s)

: Warning

R Phrase(s)

: R42/43 : May cause sensitization by inhalation and skin contact.

S Phrase(s)

: S22 : Do not breathe dust.

S24/25

: Avoid contact with skin and

SECTION 16- OTHER INFORMATION

Further information

: Revision - See : *

List of relevant R phrases

: R42/43: May cause sensitization by inhalation and skin contact.