Safety Data Sheet **Revision No.:** 00

Azithromycin for oral suspension USP
Strength: 100mg/5mL and 200mg/5mL
Pack Size: 100mg/5mL: HDPE Bottle Pack of 300mg/bottle
200mg/5mL: HDPE Bottle Pack of 600mg/bottle, 900mg/bottle and 1200mg/bottle

EMERGENCY OVERVIEW

Azithromycin for oral suspension USP, 100 mg/ 5mL or 200 mg/5 mL [each teaspoonful (5 mL) contains Azithromycin Dihydrate equivalent to Azithromycin USP, 100 mg or 200 mg]) of Azithromycin contains intended for oral administration. Azithromycin and excipients generally considered non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

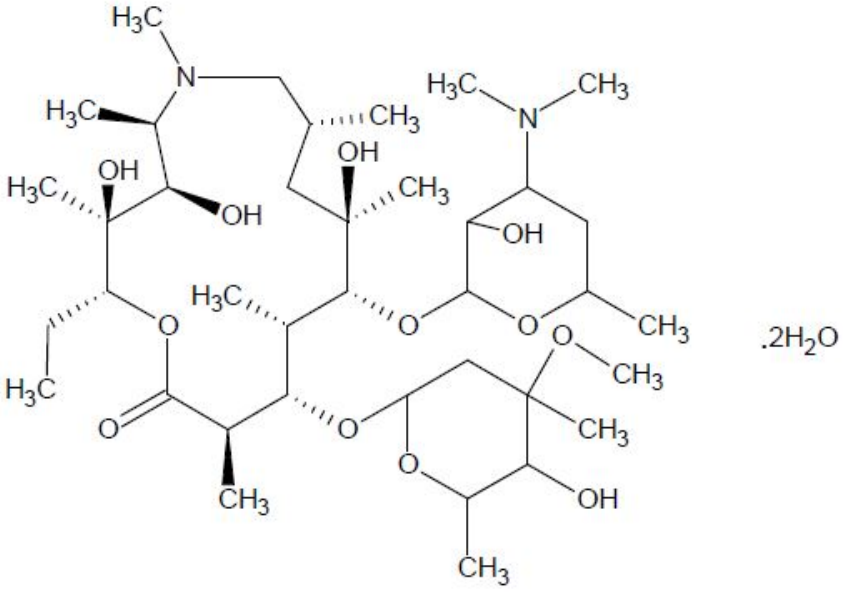
Section 1. IDENTIFICATION

Identification of the product

Product Name: Azithromycin for oral suspension USP

Formula: $C_{38}H_{72}N_2O_{12}.2H_2O$

Chemical Name: 9–Deoxo–9a–aza–9a–methyl–9a–homoerythromycinAdihydrate, N-methyl-11-aza-10-deoxo-10-dihydroerythromycin A



Manufacturer / Supplier identification

Company:	**Cadila Healthcare Limited Baddi, India**
Address:	Cadila Healthcare Limited, Swaraj Majra, Judi Kalan, Post - Baddi, Tehsil - Nalagarh, District - Solan, Himachal Pradesh 173205.
Contact for information:	Tel: +91-1795-246841 Fax: +91-1795-246842
Emergency Telephone No.	Tel: +91-1795-246841
Recommended use / Therapeutic Category	Macrolide.

Restriction on Use / Contraindications: Patients should not take aluminum- and magnesium-containing antacids and azithromycin simultaneously.

Section 2. HAZARD(S) IDENTIFICATION

Dose and Administration	Dosage should be individualized with careful monitoring of patient response. The recommended adult dosage for Azithromycin for Oral Suspension USP 100mg/5mL and 200mg/5mL in the treatment of Acute bacterial sinusitis is 500mg once daily for 3 days. Dosing regimen should be adjusted according to each patient's need at the discretion of the physician.
Adverse Effects	Most common adverse reactions are diarrhea (5 to 14%), nausea (3 to 18%), abdominal pain (3 to 7%), or vomiting (2 to 7%).
Over Dose Effect	Adverse reactions experienced at higher than recommended doses were similar to those seen at normal doses particularly nausea, diarrhea, and vomiting. In the event of over dosage, general symptomatic and supportive measures are indicated as required.
Contraindications	Azithromycin for Oral Suspension USP is contraindicated in Patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin.
Pregnancy Comments	There are no adequate or well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if clearly needed. Reproduction studies have been performed in rats and mice at doses up to moderately maternally toxic dose concentrations (i.e., 200 mg/kg/day). These daily doses in rats and mice, based on body surface area, are estimated to be 4 and 2 times, respectively, an adult daily dose of 500 mg. In the animal studies, no evidence of harm to the fetus due to azithromycin was found.
Pregnancy Category	Pregnancy Category B

Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Exposure Limit	CAS No.
Principle Component:		
Azithromycin Dihydrate	Not Found	117772-70-0
Inactive Ingredients:		
Sucrose	Not Found	57-50-1
Trisodium Phosphate Anhydrous	Not Found	7601-54-9
Hydroxypropyl Cellulose	Not Found	9004-64-2
Xanthan gum	Not Found	11138-66-2
FD&C Red # 40	Not Found	25956-17-6
Art Cherry Flavor	Not Found	-----
Art Ripe Banana Flavor FL	Not Found	-----

Section 4. FIRST-AID MEASURES

Inhalation	Remove to fresh air. If discomfort occurs or persists, get medical attention.
Skin contact	Remove contaminated clothing and shoes. Wash skin with soap and plenty of water. If irritation occurs or persists, get medical attention. Wash clothing and shoes before reuse.
Eye contact	Immediately flush eyes with plenty of water. If irritation occurs or persists, get medical attention.
Ingestion	If large quantities of this material are swallowed, get medical attention immediately. If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Section 5. FIRST FIGHTING MEASURES

Flash Point	Not available
Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Unusual Fire and Explosion Hazards	Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Fire Fighting Instructions	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

Section 6. ACCIDENTAL RELEASE MEASURES

Spill Clean Up Procedures	Use proper personal protective equipment and clothing. Shut off the source of the spill or leak if it is safe to do so. Scoop or shovel spilled material into a suitable labeled open head drum. Secure the drum cover and move the container to a safe holding area. Wash spill area thoroughly with soapy water.
Treatment and Disposal	Decontaminate equipment. Dispose of protective clothing with spilled material.
Environmental precautions	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

Section 7. HANDLING AND STORAGE

Storage	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight container. Store dry powder at 20º to 25ºC (68º to 77ºF); excursions permitted between 15º to 30ºC (59º to 86ºF) [See USP Controlled Room Temperature]. Store constituted suspension between 5°C to 30°C (41° to 86°F).
Precautions for safe handling	Avoid prolonged exposure. Avoid contact with eyes. Avoid release to environment. Use with adequate ventilation. When handling, use proper personal protective equipment. Wash thoroughly after handling. Keep container tightly closed when not in in use.

Section 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory Protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Skin protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves and protective clothing.
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Biological limit values	No biological exposure limits noted for the ingredients(s).
Exposure guidelines	General ventilation normally adequate.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Powder
Color	White to off-white
Odor	Cherry and Banana
Pure/Mixture	Mixture

Section 10. STABILITY AND REACTIVITY

Stability	Normally stable but formation of toxic gases is possible during heating or in case of fire.
Incompatibility materials to avoid	keep away from Oxidizing agents
Polymerization	No
Conditions of Polymerization	Will not occur

Section 11. TOXILOGICAL INFORMATION

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	May cause an allergic skin reaction.
Eye contact	Direct contact with eyes may cause temporary irritation.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Not classifiable as to carcinogenicity to humans. Azithromycin has shown no mutagenic potential in standard laboratory tests: mouse lymphoma assay, human lymphocyte clastogenic assay, and mouse bone marrow clastogenic assay. No evidence of impaired fertility due to azithromycin was found in rats given daily doses up to 10 mg/kg (approximately 0.2 times an adult daily dose of 500 mg based on body surface area).

Section 12. ECOLOGICAL INFORMATION

Do not allow product to enter drinking water supplies, wastewater or soil.

Section 13. DISPOSAL CONSIDERATION

Disposal Recommendations	Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. TRANSPORT INFORMATION

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG).

Section 15. REGULATORY INFORMATION

Generic Medicine, ANDA Number 211147

Section 16. OTHER INFORMATION

Additional Information

NFPA Rating: These ratings are based on NFPA code 704 and are intended for use by emergency personnel to determine the immediate hazards of a material

Health……..0

Fire……..0

Reactivity…0

Date of issue: August 04, 2018 **Supersedes edition:** New Edition

The information presented in the safety data sheet is, to the best our knowledge, accurate and reliable. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.