# SAFETY DATA SHEETS

## This SDS packet was issued with item:

078949085

N/A

# SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

### Material Name: Azithromycin Tablets

**Trade Name:** Azithromycin

**Chemical Family:** Mixture

**Intended Use:** Pharmaceutical product used as antibiotic agent

Manufacturer Information

Company name: CSPC Ouyi Pharmaceutical Co., Ltd.

Address No.276 Zhongshan West Road Shijiazhuang 050051, China

Telephone + 86-311-87896575

Website www.ouyipharma.com

Emergency phone number +1-877-436-7220

## 2. HAZARDS IDENTIFICATION

**Appearance:**

Red, modified oval-shaped, film-coated tablets, debossed with “OE” on one side and “250”,“500” or “600” on the other side.

**Statement of Hazard:** Non-hazardous in accordance with international standards for workplace safety.

**Short Term:** Dust may cause irritation if tablets are crushed or broken. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

**Known Clinical Effects:** May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain.

**EU Indication of danger:** Not classified

**Australian Hazard Classification (NOHSC):**

Non-Hazardous Substance. Non-Dangerous Goods.

**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Hazardous**

**Ingredient CAS Number EU EINECS/ELINCS List Classification %**

Azithromycin dihydrate 117772-70-0 Not listed Not Listed 56

Starch, pregelatinized 9005-25-8 232-679-6 Not Listed *

Sodium lauryl sulfate 151-21-3 205-788-1 Not Listed *

Magnesium stearate 557-04-0 209-150-3 Not Listed *

**Ingredient CAS Number EU EINECS/ELINCS List Classification %**

Calcium phosphate dibasic, anhydrous 7757-93-9 231-826-1 Not Listed *

Croscarmellose sodium 74811-65-7 Not listed Not Listed *

**Additional Information:** * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 4. FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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

**Fire / Explosion Hazards:** Not determined

## 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

**Measures for Environmental Protections:**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:**

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

**General Handling:** Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Storage Conditions:** Store as directed by product packaging.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Refer to available public information for specific member state Occupational Exposure Limits.**

**Analytical Method:** Analytical method available for Azithromycin. Contact Pfizer Inc for further information.

**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.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

10 mg/$m_3$ TWA

**Spain OEL - TWA** Listed

**Calcium phosphate dibasic, anhydrous**

**Latvia OEL - TWA** Listed

**Australia TWA** 10 mg/m3

**Sodium lauryl sulfate**

**Azithromycin dihydrate**

**Pfizer OEL TWA-8 Hr:** 0.3 mg/m³

**Belgium OEL - TWA**

**Magnesium stearate**

Listed

**ACGIH Threshold Limit Value (TWA)** 10 mg/m3 TWA

**Australia TWA** 10 mg/m3

**Bulgaria OEL - TWA** Listed

**Belgium OEL - TWA** Listed

**Ireland OEL - TWAs** Listed

**Pfizer OEL TWA-8 Hr:**

**Lithuania OEL - TWA** Listed

**Czech Republic OEL - TWA** Listed

**Portugal OEL - TWA** Listed

500µg/m3

**Spain OEL - TWA** Listed

**Greece OEL - TWA**

**Sweden OEL - TWAs** Listed

Listed

**Ireland OEL - TWAs** Listed

**Starch, pregelatinized**

**Revision date: 08-Sep-2009**

**OSHA - Final PELS - TWAs:** 15 mg/m3 total

5 mg/m3

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE).

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Polymerization:** Will not occur

## 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

## 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Acute Toxicity: (Species, Route, End Point, Dose)**

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

**Irritation / Sensitization: (Study Type, Species, Severity)**

Rat Oral LD50 1288 mg/kg

**Color:** White to off-white

**Azithromycin dihydrate**

Mouse (F) Oral LD50 4000 mg/kg

**Molecular Formula:** Mixture

Mouse (M) Oral LD50 3000 mg/kg

Rat Oral LD50 > 2000 mg/kg

**Molecular Weight:** Mixture

**Magnesium stearate**

**Sodium lauryl sulfate**

Rat Oral LD50 > 2000 mg/kg

Eye Irritation Rabbit Severe

Rat Inhalation LC50 > 2000 mg/$m_3$

**Physical State:** Film-coated tablets

**Sodium lauryl sulfate**

## 11. TOXICOLOGICAL INFORMATION

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**

**Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))**

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 12. ECOLOGICAL INFORMATION

**Environmental Overview:** In the environment, the active ingredient in this formulation is expected to mainly reside in the aquatic environment and slowly degrade.

**Mobility, Persistence and**

**Degradability:**

Azithromycin half life < 28 days (Aerobic Biodegredation - Water)

**Bioaccumulation and Toxicity:** The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. See aquatic toxicity data, below.

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**

**Aquatic Toxicity Comments:** A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an

acute ecotoxicity value (i.e. LC/EC50) is not achievable.

**Bacterial Inhibition: (Species, Method, End Point, Duration, Result)**

*In Vitro* Cytogenetics Human Lymphocytes Negative

1 Month(s) Rat Intravenous 5 mg/kg/day NOEL Liver

1 Month(s) Dog Intravenous 5 mg/kg/day NOEL Liver

Antigenicity- Passive cutaneous anaphylaxis Rabbit Negative

**Azithromycin dihydrate**

Antigenicity- Passive cutaneous anaphylaxis Mouse Negative

Reproductive & Fertility Rat Oral 10 mg/kg/day NOEL Fertility

Skin Irritation Rabbit Severe

Prenatal & Postnatal Development Mouse Oral 40 mg/kg/day NOEL Not Teratogenic

**Azithromycin dihydrate**

Prenatal & Postnatal Development Rat Oral 40 mg/kg/day NOEL Not Teratogenic

*Daphnia Magna* OECD EC50 48 Hours 120 mg/L

**Azithromycin dihydrate**

Hyallela azteca OECD LC50 96 Hours > 120 mg/L

**Azithromycin dihydrate**

Rainbow Trout OECD LC50 96 Hours > 84 mg/L

**Azithromycin dihydrate**

Green Algae OECD EC50 72 Hours 0.0037 mg/L

6 Month(s) Rat Oral 10 mg/kg/day LOEL Liver

Bacterial Mutagenicity (Ames) *Salmonella* Negative

*In Vivo* Cytogenetics Mouse Lymphoma Negative

6 Month(s) Dog Oral 10 mg/kg/day LOEL Liver

*In Vitro* Cytogenetics Mouse Negative

Antigenicity- Active anaphylaxis Guinea Pig Negative

## 12. ECOLOGICAL INFORMATION

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## 14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

**EU Indication of danger:** Not classified

**OSHA Label:**

Non-hazardous in accordance with international standards for workplace safety.

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information

required by the CPR.

**Starch, pregelatinized**

**Inventory - United States TSCA - Sect. 8(b)** Listed

*Trichoderma viride* (Fungus) OECD MIC > 1000 mg/L

**Australia (AICS):** Listed

**Material Name: Azithromycin Tablets**

**REACH - Annex IV - Exemptions from the**

**obligations of Register:**

Present

*Clostridium perfingens* (Bacterium) OECD MIC 2.0 mg/L

**EU EINECS/ELINCS List** 232-679-6

**Calcium phosphate dibasic, anhydrous**

*Bacillus subtilis* (Bacterium) OECD MIC2.0 mg/L

**Azithromycin dihydrate**

*Aspergillus niger* (Fungus) OECD MIC > 1000 mg/L

## 15. REGULATORY INFORMATION

## 16. OTHER INFORMATION

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

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Prepared by: CSPC Ouyi Pharmaceutical Co., Ltd.

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