



# Standard Pharmaceutical Product Information (Rx Product Only)

Introduction Type:  Final Version  Date: 1/2/2020

Post Launch Change

**SPECIAL HANDLING AND STORAGE REQUIREMENTS\***

a. Temperature - Indicate the USP temperature range for this product.  
 Temperature Range: \_\_\_\_\_  
 Controlled Room - between 20 and 25 C (68° - 77° F)  
 Other Temperature Range Requirement (write in): \_\_\_\_\_

is this product to be shipped to customers on ice?  No  No  
 is this product to be shipped to customers on dry ice?  No  No

b. Contact for temperature excursion questions:  
 Name: Mat Mathis  
 Number: (815)924-7685  
 Group E-mail: druginfo@lagipharma.com

c. Special regulations for product in any states?  
 Special returns requirements for this product?  No  No  
 Yes  No

d. Store product (unit of sale) upright?  
 Protect product (unit of sale) from light?  Yes  No  
 Initial shelf life at launch (if different): \_\_\_\_\_ Months

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**PRODUCT INFORMATION**

Company Name: TARGI Pharma, Inc.  
 Application: ANCA  
 Application Number for NDA/ANDA/BLA (drug): PMA161013 (med device)  
 DUNS: 983322580  
 Proprietary Name (if Applicable) and Established Name: Azithromycin Tablets, USP  
 Selling Unit NDC: 51224-122-03 Individual Unit NDC:  
 UDI: \_\_\_\_\_  
 Description: Azithromycin Tablet, USP 500mg 3 Count Blister  
 Active Ingredient(s): Azithromycin Dihydrate  
 URL for Additional Product Information: www.lagipharma.com  
 Address: 722 Progressive Lane  
 City: South Beloit  
 State: IL Zip: 61080  
 Key Contact: Pleace Dewey  
 Phone Number: (815)924-7685  
 Product Therapeutic Classification: Antibiotic

**ORDER INFORMATION**

Unit of Sale:  Bottle  Box/ Carton  Ampule  Glass  Tube  Vial Liquid Sgl  Vial Liquid Multi  Vial Powder Sgl  Vial Powder Multi  Other: Write In Blister

What is the NDC selling unit? (Write-in, e.g. 1 Box of 10 Vials) 1x3 Blister

Minimum order quantity? \_\_\_\_\_

If Yes, how many of which package type? Each: \_\_\_\_\_ Inner/ Carton/ Pack: 1 Case: \_\_\_\_\_

**PHARMACY ORDER / BILL UNIT**

Rx billing unit to pharmacy: \_\_\_\_\_  
 Rec. unit to customer? \_\_\_\_\_  
 (Write-in, e.g. 1 Vial) \_\_\_\_\_

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**ADDITIONAL PRODUCT INFORMATION**

Is the Product... a legend device?  No  No  Yes  
 reverse numbered?  No  Yes  
 Is the Product... co-licensed?  No  Yes  
 Is the Product... Directed And Drop-Ship Unit of Use?  No  Yes

If Unit Dose, is item bar coded to unit dose for hospital scanning?  No  Yes  
 If Unit Dose NDC, indicate NDC here: \_\_\_\_\_

Country of Origin: China

Is this product covered under the Trade Agreements Act (TAA)?  No  Yes

**PRODUCT DESCRIPTION INFORMATION**

Size: 3  
 Strength: 500mg  
 Dosage Form: tablets  
 Product Shape: oval  
 Product Color: red  
 Product Imprint: OE on one side & 500 on the other side

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**FOR GENERIC DRUG PRODUCTS**

Authorized Generic  \*If Authorized Generic, other section fields are not applicable

**DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) INFORMATION**

Does supplier meet DSCSA definition of manufacturer?  No  Yes  
 Is product exempt from DSCSA?  No  Yes  
 If yes, select exemption:  
 Other exemption - Write in: \_\_\_\_\_  
 Is product repackaged?  No  Yes  
 Is product sold by manufacturer's exclusive distributor?  No  Yes  
 Has FDA granted waiver/exemption/exemption for product?  No  Yes

**ITEM AND PACKING INFORMATION**

Item:	Weight Lbs.	Dimensions (US mens.) Depth Height Width	Volume (Cube)	# Pieces:
Box/ Carton/ Bundle/ Inner Pack:	0.07	1.97 0.98 4.17	8.050902	1
Case:	0.7	16.7 0.98 4.17	80.50602	10
Pallet:	21	21.65 12.96 11.02	3099.19317	300
UPC:	Case:	Carton:		0

**COST INFORMATION**

Regular Cost Invoice Cost (WAC) (\$): \$13.30  
 Vendor #: \_\_\_\_\_  
 Federal Excise Tax Per Unit of Sale: \_\_\_\_\_  
 As of date: 1/2/2020  
 Wholesaler Use Only: \_\_\_\_\_  
 Signature: Pleace Dewey

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**GTIN PRODUCT INFORMATION**

Item	Level	Scaleable Unit	Quantity
<input checked="" type="checkbox"/>	2D	Linear	1
<input checked="" type="checkbox"/>	2D	Linear	10
<input checked="" type="checkbox"/>	2D	Linear	300
<input checked="" type="checkbox"/>	2D	Linear	30351224122031
<input checked="" type="checkbox"/>	2D	Linear	30351224122032
<input checked="" type="checkbox"/>	2D	Linear	50351224122038

**GTIN-14**

00351224122031  
 30351224122032  
 50351224122038

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**Serialized?**  
 If not, when? \_\_\_\_\_  
 Items aggregated? \_\_\_\_\_

Attach copy of SAFETY DATA SHEET (SDS) or non hazard letter, PACKAGE INSERT, LABEL AND PHOTO OF PRODUCT PACKAGING and BARCODE.  
 \*Please provide any additional information on page 2.



# Standard Pharmaceutical Product Information (Page 2)

For Designated Drop Ship Only Products, Please Use Page 3  
MATERIAL HAZARD CLASSIFICATION and TRANSPORTATION

Is this product (check all that apply):

- a. Cytotoxic?  No
- b. CA Prop. 65 Carcinogen or Reproductive Toxicant?  
Is the product a CA Prop 65 carcinogen?  
Is the product a CA Prop 65 reproductive toxicant?  
Does the product label bear a CA Prop 65 warning?  No

- c. Contact Hazard?  No
- d. Does this product require special clean-up instructions?  
(If yes, attach SDS with special instructions.)  No
- e. Does the product contain DEHP?  No

Is this product regulated for shipment by DOT or IATA?

(If yes, answer a-e below and provide SDS)

- a. UN/Identification Number
- b. Proper Shipping Name
- c. DOT Hazard Class
- d. Packing Group
- e. Inhalation Hazard?  No

Is the product restricted for air shipment? If so, indicate restriction:

- Passenger
- Cargo
- Passenger & Cargo

Is this a reportable quantity?  No

RQ Threshold:  No

Is this a marine pollutant?  No

Is this product shipped utilizing an authorized DOT exception or Special Permit?

No (if yes, identify method below)

- Limited Quantity
- Consumer Commodity, ORM-D
- Small Quantity (49 CFR 173.4)
- Special Permit: DOT-SP
- Special Provision (listed in Column 7 of 49 CFR 172.101):  
SP#

### ADD'L STORAGE INFORMATION

Is the Product...

- Controlled Substance?  No
- Controlled by State(s)?  No
- ARCOS Reportable?  No
- Schedule No. (inc. N for non-narcotic)
- Controlled Substance Code
- Listed Chemical (List I or II)
- If yes, indicate which:
- Is it a scheduled listed chemical product?  No

### CLASS OF TRADE RESTRICTION:

No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices

Restricted to retail pharmacy only:  Yes

Restricted to hospital, clinics, and physician offices only:  No

Restricted from US territories? (explain in comments)  No

Comments:

### SDS Hazard Classification

- Organic
- Corrosive
- Inorganic
- Oxidizer
- Steroid/Androgen
- Contact Hazard

Aerosol Class: Identify NFPA Storage Level:

Is the product a NIOSH hazardous drug?  
If yes, indicate which:  No

### Hazardous Waste Identification

EPA Hazardous Waste Code:

### REMS or REGISTRY RESTRICTIONS

Is there a REMS on this product?  
If Yes, is it managed with a pharmacy registry?  
Website URL:  No

Comments / Details: (For example, iPledge program?)

### REMS:

- No
- REMS Program Manager Name:  Phone:
- Supplier Manages REMS registry exclusively:
- Wholesale distributor support:
- Provider Name:
- Site Enrollment Number assigned by Supplier:
- DEA #:
- PCPDF #:
- NPI #:

Comments

Registry:

Registry Program Contact Name:

Phone:

### RETURN INSTRUCTIONS

Contact tel. # if product received damaged:

Is product returnable for credit:  Yes

URL/Link to returns policy:

Special regulations or returns requirements for this product in certain states?  Yes

If so, which states? Other requirements? Comments?

(Georgia, Mississippi, and North Carolina. Requests can be made via fax: (815)624-0608 or email: customercare@tagpharma.com)

MISCELLANEOUS NOTES and/or Image of Product Barcode:

Release DATE



# Standard Pharmaceutical Product Information (Page 3)

FOR DESIGNATED DROP SHIP PRODUCT ONLY - if not a designated drop ship, do not complete.

Order Method for Designated Drop Ship Product	Standard Order Receipt and Processing										
<p>Purchase orders may be accepted by:</p> <p>a. EDI <input type="checkbox"/> Yes</p> <p>b. Autofax <input type="checkbox"/> Yes      Fax Number: (815)624-0608</p> <p>c. Fax <input type="checkbox"/> Yes      Fax Number: (815)624-0608</p> <p>d. Phone only <input type="checkbox"/> No      Phone No.: (855)225-8244</p> <p>e. Supplier Web Site only <input type="checkbox"/> No      Site Address:</p> <p>Minimum Order Quantity: 1 case</p> <p>Supplier's Customer Service Number: (855)225-8244</p> <p>Contracted 3PL company / contact #: _____ Name: _____ Phone: _____</p>	<p><b>Purchase order daily receipt cut off time by supplier</b></p> <p>Cut off time: <input type="text" value="12:00pm"/> Central</p> <p>Shipping lead time of PO: <input type="text"/> Hours      <input type="text"/> Days</p> <p>Ships same day for next day receipt: <input type="checkbox"/> No</p> <p>Ships for second day receipt: <input type="checkbox"/> No</p> <p>Ships regular ground for 3-10 days receipt: <input type="checkbox"/> Yes</p>										
Expedited Freight Charges or Other Designated Drop Ship Fees:	Overnight and Priority Overnight P.O. Processing										
<p>Expedited freight fees billed with each order: <input type="checkbox"/> Yes</p> <p>Drop Ship service fee billed with each order: <input type="checkbox"/> No</p> <p>Drop Ship miscellaneous fees billed: <input type="checkbox"/> No</p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p><b>Overnight receipt available:</b> <input type="checkbox"/> Yes</p> <p>PO Receipt cut off time: <input type="text" value="12:00pm"/> Central</p> <p>Days of week overnight is available:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>Monday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Tuesday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Wednesday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Thursday</td><td><input checked="" type="checkbox"/></td></tr> <tr><td>Friday</td><td><input type="checkbox"/></td></tr> </table> <p><b>Priority Overnight receipt available:</b> <input type="checkbox"/> Yes</p> <p>PO Receipt Cut off time: <input type="text" value="12:00pm"/></p> <p><b>Saturday Overnight receipt available:</b> <input type="checkbox"/> No</p> <p>PO Receipt Cut off time: <input type="text" value="(855)225-8244"/></p> <p>Phone: <input type="text" value="(855)225-8244"/> Phone #: <input type="text" value="(815)624-0608"/></p> <p>Order receipt method: Fax: <input type="checkbox"/> Yes      Fax #: <input type="text"/></p> <p>EDI: <input type="checkbox"/> Yes</p> <p>Overnight Fees apply: <input type="checkbox"/> Yes</p> <p>Other fees apply: <input type="checkbox"/></p>	Monday	<input checked="" type="checkbox"/>	Tuesday	<input checked="" type="checkbox"/>	Wednesday	<input checked="" type="checkbox"/>	Thursday	<input checked="" type="checkbox"/>	Friday	<input type="checkbox"/>
Monday	<input checked="" type="checkbox"/>										
Tuesday	<input checked="" type="checkbox"/>										
Wednesday	<input checked="" type="checkbox"/>										
Thursday	<input checked="" type="checkbox"/>										
Friday	<input type="checkbox"/>										
Class of Trade Restriction:	Return Instructions										
<p>No restriction: Select YES if sold to retail pharmacy, hospitals, clinics and physician offices <input type="checkbox"/> Yes</p> <p>Restricted to retail pharmacy only: <input type="checkbox"/> No</p> <p>Restricted to hospital, clinics, and physician offices only: <input type="checkbox"/> No</p> <p>Restricted from US territories? (explain in comments) <input type="checkbox"/> No</p> <p>Comments: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Contact # if product is received damaged: <input type="text" value="(855)225-8244"/> Yes</p> <p>Is product returnable for credit: <input type="checkbox"/> Yes</p> <p>URL/link to returns policy: <input type="text"/></p> <p>Special regulations or returns requirements for this product in certain states? <input type="checkbox"/> Yes</p> <p>If so, which states? Other requirements? Comments? <input type="text" value="Georgia, Mississippi, and North Carolina. Requests can be made via fax: (815)624-7687 or em"/></p>										
Other Data Information Required to Process PO:	ADDITIONAL INFORMATION										
<p>Patient Procedure Date: <input type="text"/></p> <p>Physician Name: <input type="text"/></p> <p>Physician/Clinic Phone #: <input type="text"/></p> <p>Physician State License #: <input type="text"/></p> <p>Physician/Clinic DEA #: <input type="text"/></p> <p>Physician/Clinic Specialty: <input type="text"/></p> <p>Miscellaneous Notes: <input style="width: 100%; height: 40px;" type="text"/></p>	<p>Is product order for scheduled patient procedure? <input type="checkbox"/></p> <p>Is product order for restocking purposes? <input type="checkbox"/></p>										

# 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](http://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 turnout 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<sup>3</sup> TWA

**Spain OEL - TWA** Listed

**Calcium phosphate dibasic, anhydrous**

**Latvia OEL - TWA** Listed

**Australia TWA** 10 mg/m<sup>3</sup>

**Sodium lauryl sulfate**

**Azithromycin dihydrate**

**Pfizer OEL TWA-8 Hr:** 0.3 mg/m<sup>3</sup>

**Belgium OEL - TWA**

**Magnesium stearate**

Listed

**ACGIH Threshold Limit Value (TWA)** 10 mg/m<sup>3</sup> TWA

**Australia TWA** 10 mg/m<sup>3</sup>

**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/m<sup>3</sup>

**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/m<sup>3</sup> total

5 mg/m<sup>3</sup>

## **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<sup>3</sup>

**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 Biodegradation - 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 perfringens* (Bacterium) OECD MIC 2.0 mg/L

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

**Calcium phosphate dibasic, anhydrous**

*Bacillus subtilis* (Bacterium) OECD MIC 2.0 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.

Issue Date: 09/2017

Prepared by: CSPC Ouyi Pharmaceutical Co., Ltd.

DISCLAIMER: This information is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes.