MATERIAL SAFETY DATA SHEET

Product Name: Azithromycin for Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Azithromycin for Injection

Synonyms
(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-dideoxy-3-C-methyl-3-O-methyl-
α-L-ribo-hexopyranosyloxy)-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-
heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyloxy]-
1-oxa-6-azacyclopentadecan-15-one monohydrate.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Azithromycin Monohydrate

Chemical Formula
C_{38}H_{72}N_{2}O_{12} • H_{2}O

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
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<tbody>
<tr>
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<td>121479-24-4</td>
<td>NA</td>
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<tr>
<td>Sodium Hydroxide</td>
<td>17</td>
<td>1310-73-2</td>
<td>WB4900000</td>
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<td>Citric Acid Anhydrous</td>
<td>36</td>
<td>77-92-9</td>
<td>GE7350000</td>
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3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
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<tbody>
<tr>
<td>Azithromycin Monohydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Citric Acid Anhydrous</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Azithromycin for Injection is a powder containing lyophilized azithromycin monohydrate, a macrolide antibiotic with actions and indications similar to erythromycin. It is used to treat respiratory-tract infections, skin and soft-tissue infections, and uncomplicated genital infections. In the workplace, the powdered product should be considered potentially irritating to the skin and respiratory tract, and possibly corrosive to the eyes. Based on clinical use, possible target organs include the skin, eyes, gastrointestinal system, cardiovascular system and liver.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposure. Some macrolides are irritating to the eyes. In clinical
Product Name: Azithromycin for Injection

use, adverse effects may include abdominal pain and cramps, nausea, vomiting, and diarrhea. Liver dysfunction has been reported occasionally. Macrolides have been associated with QT prolongation and ventricular arrhythmias, including ventricular tachycardia and torsades de pointes. Reversible high frequency hearing loss has also been reported with some macrolides in patients with renal insufficiency. Allergic reactions (mostly rashes, pruritus, and urticaria; infrequently anaphylactoid/respiratory) have been clinically evident in a small number of treated patients. Prolonged therapy can result in overgrowth of non-susceptible bacteria/fungi.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to macrolide antibiotics; pre-existing gastrointestinal, cardiovascular, or liver ailments.

4. FIRST AID MEASURES

Eye contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability None anticipated from this product. However, many organic powders will combust at high temperatures.

Fire & Explosion Hazard None anticipated from this product. Avoid the creation of dusty environments.

Extinguishing media As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect powder using techniques that minimize the creation of airborne dust. If spill occurs after reconstitution, absorb any liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required under conditions of normal product use.
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Storage

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions

No special precautions are required for hazard controls. Employees with known allergies to macrolide antibiotics should consult a health and/or safety professional prior to working with open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m3</th>
<th>ppm</th>
<th>µg/m3</th>
<th>Note</th>
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<tbody>
<tr>
<td>Citric Acid Anhydrous</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
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<tr>
<td>Azithromycin Monohydrate</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>US OSHA 8 Hr PEL</td>
<td>2</td>
<td>N/A</td>
<td>N/A</td>
<td>8hr TWA</td>
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<tr>
<td>Sodium Hydroxide</td>
<td>ACGIH Ceiling</td>
<td>2</td>
<td>N/A</td>
<td>N/A</td>
<td>8hr TWA</td>
</tr>
</tbody>
</table>

Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State: Solid
Color: White crystalline powder
Odor: NA
Odor Threshold: NA
pH: (9.0-11.0) for 0.2% mix of (1:1) methyl alcohol and water
Melting point/Freezing point: NA
Initial Boiling Point/Boiling Point Range: NA
Evaporation Rate: NA
Flammability (solid, gas): NA
Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density: NA
**Product Name: Azithromycin for Injection**

**Specific Gravity:** NA
**Solubility:** Soluble in water; freely soluble in dehydrated alcohol and in dichloromethane.
**Partition coefficient: n-octanol/water:** 4.02
**Auto-ignition temperature:** NA
**Decomposition temperature:** NA

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### 10. STABILITY AND REACTIVITY

**Reactivity**  
Not determined

**Chemical Stability**  
Stable under standard use and storage conditions

**Hazardous Reactions**  
Not determined

**Conditions to avoid**  
Not determined

**Incompatibilities**  
Not determined

**Hazardous decomposition products**  
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

**Hazardous Polymerization**  
Not anticipated to occur with this product.

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### 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity**  
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
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<tbody>
<tr>
<td>Azithromycin</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;2000</td>
<td>mg/kg</td>
<td>Rat Mouse</td>
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<tr>
<td></td>
<td></td>
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<td>3000</td>
<td>mg/kg</td>
<td></td>
<td></td>
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<tr>
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<td></td>
<td>3000</td>
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<td>Rat Mouse</td>
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<td>5040</td>
<td>mg/kg</td>
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<td>Citric Acid</td>
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<td>LD50</td>
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<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td>Sodium Hydroxide</td>
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<td>LDLo</td>
<td>Oral</td>
<td>500</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
</tbody>
</table>

**Aspiration Hazard**  
None anticipated from normal handling of the intact product.

**Dermal Irritation/Corrosion**  
None anticipated from normal handling of the intact product. However, inadvertent contact with this product formulation may be irritating to the skin. Sodium hydroxide produced severe skin irritation in a study in rabbits. Citric acid produced mild irritation in a study in rabbits.

**Ocular Irritation/Corrosion**  
None anticipated from normal handling of the intact product. However, inadvertent contact of this product formulation with eyes may produce irritation, redness and pain. Sodium hydroxide produced severe eye irritation in a study in rabbits. Citric acid also produced severe eye irritation in a study in rabbits.
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Dermal or Respiratory Sensitization
None anticipated from normal handling of the intact product. Serious allergic reactions, including angioedema, anaphylaxis and dermatologic reactions including Steven Johnson Syndrome and toxic epidermal necrolysis have been reported rarely in patients on azithromycin therapy. Allergic reactions occur in a small percentage of the population given therapeutic doses of macrolide antibiotics, estimated to be

Reproductive Effects
No evidence of impaired fertility due to azithromycin was found in animal studies. Reproduction studies have been performed in rats and mice at doses up to moderately maternally toxic dose concentrations (i.e., 200 mg/kg/day by the oral route). These doses, based on a mg/m² basis, are estimated to be 4 and 2 times, respectively, the human daily dose of 500 mg by the oral route. In the animal studies, no evidence of harm to the fetus due to azithromycin was found.

Mutagenicity
Azithromycin was not mutagenic in standard laboratory tests: mouse lymphoma assay, human lymphocyte clastogenic assay, and mouse bone marrow clastogenic assay.

Carcinogenicity
Long-term studies in animals to evaluate carcinogenic potential of azithromycin have not been conducted.

Target Organ Effects
Based on clinical use, possible target organs include the possible target organs include the skin, eyes, gastrointestinal system, cardiovascular system and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product.

LC50(48hr, flow through) = 189 mg/l in freshwater fish for sodium hydroxide
LC50(24hr, static) = 125-160 mg/l in freshwater fish for sodium hydroxide
LC50(48hr, static) = 125 mg/l in freshwater fish for sodium hydroxide
LC50(96hr static) = 45.4 – 125 mg/l in freshwater fish for sodium hydroxide
EC(lethality) = 100 - 156 mg/l in Daphnia for sodium hydroxide

LC50(96hr, static) = 444-760 mg/l and 1516 mg/l in freshwater fish for citric acid
LC50(48hr, static) = 2600 mg/l in freshwater fish for citric acid.
EC50(72hr) ~ 120 mg/l in Daphnia magna for citric acid
EC3(7 day) = 640 mg/l in Scenedesmus quadricauda (algae) for citric acid.
EC50 > 10,000 mg/l in Pseudomonas putida (bacteria) for citric acid

Persistence/Biodegradability
Not determined for product.

Bioaccumulation
Not determined for product.

Mobility in Soil
Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized by the waste generator. Further, disposal of all pharmaceuticals should be performed in accordance with the federal, state or local regulatory requirements.
Product Name: Azithromycin for Injection

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated
IMDG STATUS: Not regulated
ICAO/IATA STATUS: Not regulated
Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
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<tbody>
<tr>
<td>Azithromycin Monohydrate</td>
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<td>Not Listed</td>
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</tr>
<tr>
<td>Sodium Hydroxide</td>
<td>Listed</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

RCRA Status: Not Listed
U.S. OSHA Classification:
Possibly Corrosive
Possible Skin Irritant
Target Organ Toxin

GHS Classification:
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class: Not Applicable
Hazard Category: Not Applicable
Signal Word: Not Applicable
Symbol: Not Applicable
Prevention: P260 - Do not breathe dust/fume/gas/mist/vapors'/spray.
Hazard Statement: Not Applicable
Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*
Product Name: Azithromycin for Injection

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Azithromycin Monohydrate.

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases:
S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:
ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EEL Employee Exposure Limit
IATA International Air Transport Association
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health
OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65 California Proposition 65
RCRA US EPA, Resource Conservation and Recovery Act
RTECS Registry of Toxic Effects of Chemical Substances
SARA Superfund Amendments and Reauthorization Act
STEL 15-minute Short Term Exposure Limit
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 09/22/2011
Obsolete Date: 06/22/2009

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