



# MATERIAL SAFETY DATA SHEET

Revision date: 05-Jan-2007

Version: 2.3

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161

Emergency telephone number:  
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

**Material Name: Zithromax® (Azithromycin) for injection**

**Trade Name:** Zithromax(R)  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as antibiotic agent

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

| Ingredient             | CAS Number  | EU EINECS List | %  |
|------------------------|-------------|----------------|----|
| Azithromycin dihydrate | 117772-70-0 | Not listed     | 50 |
| Citric acid            | 77-92-9     | 201-069-1      | *  |
| Sodium hydroxide       | 1310-73-2   | 215-185-5      | ** |

**Additional Information:** \* Proprietary  
\*\* to adjust pH  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

## 3. HAZARDS IDENTIFICATION

**Appearance:** White fluffy powder, lyophilized

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

**Additional Hazard Information:**  
**Short Term:** Dust may cause irritation. 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

**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.

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### 4. FIRST AID MEASURES

|                      |   |
|----------------------|---|
| <b>Eye Contact:</b>  | Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.   |
| <b>Skin Contact:</b> | Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. |
| <b>Ingestion:</b>    | Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.  |
| <b>Inhalation:</b>   | Remove to fresh air. If discomfort persists, get medical attention.   |

### 5. FIRE FIGHTING MEASURES

|                                       |   |
|---------------------------------------|---|
| <b>Extinguishing Media:</b>           | Use carbon dioxide, dry chemical, or water spray.   |
| <b>Hazardous Combustion Products:</b> | Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.  |
| <b>Fire Fighting Procedures:</b>      | During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus. |
| <b>Fire / Explosion Hazards:</b>      | Fine particles (such as dust and mists) may fuel fires/explosions.  |

### 6. ACCIDENTAL RELEASE MEASURES

|   |  |
|---|--|
| <b>Health and Safety Precautions:</b>             | Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.   |
| <b>Measures for Cleaning / Collecting:</b>        | 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. |
| <b>Measures for Environmental Protections:</b>    | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.   |
| <b>Additional Consideration for Large Spills:</b> | 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

|                             |  |
|-----------------------------|--|
| <b>General Handling:</b>    | Use only in a well-ventilated area. Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. |
| <b>Storage Conditions:</b>  | Store out of direct sunlight in a well ventilated area at room temperature.  |
| <b>Storage Temperature:</b> | Store as directed by product packaging.  |

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|  |  |
|--|--|
| <b>Azithromycin dihydrate</b><br>Pfizer OEL TWA-8 Hr:                                  | 0.5 mg/m <sup>3</sup>                                |
| <b>Sodium hydroxide</b><br>OSHA - Final PELS - TWAs:<br>ACGIH Ceiling Threshold Limit: | 2 mg/m <sup>3</sup><br>= 2 mg/m <sup>3</sup> Ceiling |

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Australia PEAK

= 2 mg/m<sup>3</sup> Peak

**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. Local and general ventilation should be used as necessary, when handling this material in bulk.

**Personal Protective Equipment:**

**Hands:** Rubber gloves  
**Eyes:** Safety glasses or goggles  
**Skin:** None required with normal use of this material. Wear protective clothing with long sleeves when working with large quantities. Wash hands and arms thoroughly after handling this material. Clean up spills immediately.  
**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:

|   |                            |                           |         |
|---|----------------------------|---------------------------|---------|
| <b>Physical State:</b>  | Fluffy powder, lyophilized | <b>Color:</b>             | White   |
| <b>Odor:</b>  | Odorless                   | <b>Molecular Formula:</b> | Mixture |
| <b>Molecular Weight:</b>  | Mixture                    |                           |         |
| <b>Solubility:</b>  | Highly soluble: Water      |                           |         |
| <b>pH:</b>  | 6.4 - 6.8 (reconstituted)  |                           |         |
| <b>Partition Coefficient (Measured; pH 6-8) Log Pow/Log Kow):</b> | 0.534                      |                           |         |

## 10. STABILITY AND REACTIVITY

**Stability:** Stable  
**Conditions to Avoid:** None known  
**Incompatible Materials:** Strong oxidizers  
**Hazardous Decomposition Products:** No data available  
**Polymerization:** Will not occur

## 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)**

**Sodium hydroxide**

Mouse IP LD50 40 mg/kg

**Citric acid**

Rat Oral LD50 3000 mg/kg

**Azithromycin dihydrate**

Mouse (F) Oral LD50 4000 mg/kg

Mouse (M) Oral LD50 3000 mg/kg

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Rat Oral LD50 > 2000 mg/kg

**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)

#### **Sodium hydroxide**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Severe

#### **Citric acid**

Eye Irritation Rabbit Severe  
Skin Irritation Rabbit Mild

#### **Azithromycin dihydrate**

Antigenicity- Active anaphylaxis Guinea Pig Negative  
Antigenicity- Passive cutaneous anaphylaxis Rabbit Negative  
Antigenicity- Passive cutaneous anaphylaxis Mouse Negative

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

#### **Azithromycin dihydrate**

6 Month(s) Rat Oral 10 mg/kg/day LOEL Liver  
6 Month(s) Dog Oral 10 mg/kg/day LOEL Liver  
1 Month(s) Rat Intravenous 5 mg/kg/day NOEL Liver  
1 Month(s) Dog Intravenous 5 mg/kg/day NOEL Liver

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

#### **Azithromycin dihydrate**

Reproductive & Fertility Rat Oral 10 mg/kg/day NOEL Fertility  
Prenatal & Postnatal Development Mouse Oral 40 mg/kg/day NOEL Not Teratogenic  
Prenatal & Postnatal Development Rat Oral 40 mg/kg/day NOEL Not Teratogenic

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

#### **Azithromycin dihydrate**

Bacterial Mutagenicity (Ames) *Salmonella* Negative  
*In Vivo* Cytogenetics Mouse Lymphoma Negative  
*In Vitro* Cytogenetics Mouse Negative  
*In Vitro* Cytogenetics Human Lymphocytes Negative

**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)

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

|  |        |
|--|--------|
| Partition Coefficient (Measured; pH 6-8) Log Pow/Log Kow): | 0.534  |
| Adsorption Coefficient (soil - Log 10 Koc):                | 59,900 |

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

#### **Azithromycin dihydrate**

|                          |      |      |          |             |
|--------------------------|------|------|----------|-------------|
| <i>Daphnia Magna</i>     | OECD | EC50 | 48 Hours | 120 mg/L    |
| <i>Hyallolela azteca</i> | OECD | LC50 | 96 Hours | > 120 mg/L  |
| Rainbow Trout            | OECD | LC50 | 96 Hours | > 84 mg/L   |
| Green Algae              | OECD | EC50 | 72 Hours | 0.0037 mg/L |

**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)

#### **Azithromycin dihydrate**

|  |      |     |             |
|--|------|-----|-------------|
| <i>Aspergillus niger</i> (Fungus)          | OECD | MIC | > 1000 mg/L |
| <i>Trichoderma viride</i> (Fungus)         | OECD | MIC | > 1000 mg/L |
| <i>Clostridium perfringens</i> (Bacterium) | OECD | MIC | 2.0 mg/L    |
| <i>Bacillus subtilis</i> (Bacterium)       | OECD | MIC | 2.0 mg/L    |

## 13. DISPOSAL CONSIDERATIONS

**Disposal Procedures:** Dispose of waste in accordance with all applicable laws and regulations.

## 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**

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## 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.

## Citric acid

|   |           |
|---|-----------|
| Inventory - United States TSCA - Sect. 8(b) | Present   |
| Australia (AICS):                           | Present   |
| EU EINECS List                              | 201-069-1 |

## Sodium hydroxide

|   |   |
|---|---|
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | = 1000 lb final RQ<br>= 454 kg final RQ |
| Inventory - United States TSCA - Sect. 8(b)                       | Present                                 |
| Australia (AICS):   | Present                                 |
| Standard for the Uniform Scheduling for Drugs and Poisons:        | Schedule 5<br>Schedule 6                |
| EU EINECS List  | 215-185-5                               |

## 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**