1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Zithromax® (Azithromycin) for injection

Trade Name: Zithromax; Zitromax; Azitromicina; Azitromax; Zitromac

Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as antibiotic agent

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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
International CHEMTREC (24 hours): +1-703-527-3887

Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification: Not classified as hazardous

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

EU Classification:

EU Indication of danger: Not classified

Other Hazards

Australian Hazard Classification (NOHSC):


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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azithromycin dihydrate</td>
<td>117772-70-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>50</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>201-069-1</td>
<td>Xi; R36</td>
<td>Eye Irrit. 2A (H319)</td>
<td>&lt;10</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>C; R35</td>
<td>Skin Corr. 1A (H314)</td>
<td>**</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed
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.
Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

5. FIRE FIGHTING MEASURES

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

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up

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.

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

Precautions for Safe Handling
Minimize dust generation and accumulation. Avoid contact with eyes, skin and clothing. Avoid breathing dust. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Azithromycin dihydrate
Pfizer OEL TWA-8 Hr: 500µg/m³

Sodium hydroxide
ACGIH Ceiling Threshold Limit: 2 mg/m³
Australia PEAK 2 mg/m³
Austria OEL - MAKs 2 mg/m³
Bulgaria OEL - TWA 2.0 mg/m³
Czech Republic OEL - TWA 1 mg/m³
Estonia OEL - TWA 1 mg/m³
France OEL - TWA 2 mg/m³
Greece OEL - TWA 2 mg/m³
Hungary OEL - TWA 2 mg/m³
Japan - OELs - Ceilings 2 mg/m³
Latvia OEL - TWA 0.5 mg/m³
OSHA - Final PELS - TWAs: 2 mg/m³
Poland OEL - TWA 0.5 mg/m³
Slovakia OEL - TWA 2 mg/m³
Slovenia OEL - TWA 2 mg/m³
Sweden OEL - TWAs 1 mg/m³
Switzerland OEL -TWAs 2 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION


Exposure Controls:

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.

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

Physical State: Fluffy powder, lyophilized
Color: White
Odor: Odorless
Odor Threshold: No data available
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
Solubility: Highly soluble: Water
pH: 6.4 - 6.8 (reconstituted)
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Sodium hydroxide
No data available
Azithromycin dihydrate
Measured 7 Log P 0.67
Citric acid
No data available
Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available
Polymerization: Will not occur
10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
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
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

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

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

Sodium hydroxide
Mouse  IP  LD50  40 mg/kg

Azithromycin dihydrate
Mouse (F)  Oral  LD50  4000 mg/kg
Mouse (M)  Oral  LD50  3000mg/kg
Rat  Oral  LD50  > 2000mg/kg

Citric acid
Rat  Oral  LD50  3000 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

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

Citric acid
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
11. TOXICOLOGICAL INFORMATION

Azithromycin dihydrate

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

Azithromycin dihydrate

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>End Point</th>
<th>Effect(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive &amp; Fertility</td>
<td>Rat</td>
<td>Oral</td>
<td>10 mg/kg/day</td>
<td>NOEL</td>
<td>Fertility</td>
</tr>
<tr>
<td>Prenatal &amp; Postnatal Development</td>
<td>Mouse</td>
<td>Oral</td>
<td>40 mg/kg/day</td>
<td>NOEL</td>
<td>Not Teratogenic</td>
</tr>
<tr>
<td>Prenatal &amp; Postnatal Development</td>
<td>Rat</td>
<td>Oral</td>
<td>40 mg/kg/day</td>
<td>NOEL</td>
<td>Not Teratogenic</td>
</tr>
</tbody>
</table>

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

Azithromycin dihydrate

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Organism</th>
<th>Inoculum</th>
<th>Method</th>
<th>End Point</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial Mutagenicity (Ames)</td>
<td>Salmonella</td>
<td>Negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In Vivo Cytogenetics</td>
<td>Mouse Lymphoma</td>
<td>Negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In Vitro Cytogenetics</td>
<td>Mouse</td>
<td>Negative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In Vitro Cytogenetics</td>
<td>Human Lymphocytes</td>
<td>Negative</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

Toxicity:

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

Azithromycin dihydrate

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water Flea)</td>
<td>OECD</td>
<td>EC50</td>
<td>48 Hours</td>
<td>120 mg/L</td>
</tr>
<tr>
<td>Hyallela azteca (Freshwater Amphipod)</td>
<td>OECD</td>
<td>LC50</td>
<td>96 Hours</td>
<td>&gt; 120 mg/L</td>
</tr>
<tr>
<td>Oncorhynchus mykiss (Rainbow Trout)</td>
<td>OECD</td>
<td>LC50</td>
<td>96 Hours</td>
<td>&gt; 84 mg/L</td>
</tr>
<tr>
<td>Green Algae</td>
<td>OECD</td>
<td>EC50</td>
<td>72 Hours</td>
<td>0.0037 mg/L</td>
</tr>
<tr>
<td>Microcystis aeruginosa (Blue-green Alga)</td>
<td>OECD</td>
<td>ErC50</td>
<td>96 Hours</td>
<td>0.0018 mg/L</td>
</tr>
</tbody>
</table>

Aquatic Toxicity Comments: A greater than (> or >) 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: (Inoculum, Method, End Point, Result)

Azithromycin dihydrate

<table>
<thead>
<tr>
<th>Inoculum</th>
<th>Method</th>
<th>End Point</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspergillus niger (Fungus)</td>
<td>OECD</td>
<td>MIC</td>
<td>&gt; 1000 mg/L</td>
</tr>
<tr>
<td>Trichoderma viride (Fungus)</td>
<td>OECD</td>
<td>MIC</td>
<td>&gt; 1000 mg/L</td>
</tr>
<tr>
<td>Clostridium perfringens (Bacterium)</td>
<td>OECD</td>
<td>MIC</td>
<td>2.0 mg/L</td>
</tr>
<tr>
<td>Bacillus subtilis (Bacterium)</td>
<td>OECD</td>
<td>MIC2.0</td>
<td>mg/L</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Material Name: Zithromax® (Azithromycin) for injection
Revision date: 01-Mar-2015

Terrestrial Toxicity: (Species, Method, End Point, Duration, Result)

Azithromycin dihydrate 
_Eisenia foetida_ (Earthworm) TAD NOEC 28 Days 1000 mg/kg

Azithromycin dihydrate 
_Pimephales promelas_ (Fathead Minnow) OECD 32 Day(s) NOEC 4.6 mg/L Survival
_Ceriodaphnia dubia_ (Daphnids) OPPTS 7 Day(s) NOEC 0.0044 mg/L Reproduction

Persistence and Degradability: No data available

Bio-accumulative Potential: 
Partition Coefficient: (Method, pH, Endpoint, Value)
Azithromycin dihydrate 
Measured 7 Log P 0.67

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: 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

The following refers to all modes of transportation unless specified below.

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

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

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.
15. REGULATORY INFORMATION

Azithromycin dihydrate

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65            | Not Listed |
| EU EINECS/ELINCS List               | Not Listed |

Citric acid

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65           | Present |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS):                   | 201-069-1 |
| EU EINECS/ELINCS List               | |

Sodium hydroxide

| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances   | 1000 lb |
| and their Reportable Quantities:   | 454 kg |
| California Proposition 65          | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS):                  | Present |
| Standard for the Uniform Scheduling| Schedule 5 |
| for Drugs and Poisons:             | Schedule 6 |
| EU EINECS/ELINCS List              | 215-185-5 |

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

- Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
- Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

C - Corrosive
Xi - Irritant

R35 - Causes severe burns.
R36 - Irritating to eyes.

Data Sources:
Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Reasons for Revision:
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 7 - Handling and Storage. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 12 - Ecological Information. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 01-Mar-2015
End of Safety Data Sheet