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

Material Name: Azithromycin Tablets

- Trade Name: Zithromax
- Chemical Family: Mixture
- Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Appearance: White to off-white film-coated tablets

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


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>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>56</td>
</tr>
<tr>
<td>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium lauryl sulfate</td>
<td>151-21-3</td>
<td>205-788-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Calcium phosphate dibasic, anhydrous</td>
<td>7757-93-9</td>
<td>231-826-1</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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.

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

Starch, pregelatinized
- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: Listed
- Bulgaria OEL - TWA: Listed
- Czech Republic OEL - TWA: Listed
- Greece OEL - TWA: Listed
- Ireland OEL - TWAs: Listed
- OSHA - Final PELS - TWAs: 15 mg/m³ total
- Portugal OEL - TWA: Listed
- Spain OEL - TWA: Listed

Calcium phosphate dibasic, anhydrous
- Latvia OEL - TWA: Listed

Sodium lauryl sulfate
- Pfizer OEL TWA-8 Hr: 0.3 mg/m³

Magnesium stearate
- ACGIH Threshold Limit Value (TWA): 10 mg/m³ TWA
- Australia TWA: 10 mg/m³
- Belgium OEL - TWA: Listed
- Ireland OEL - TWAs: Listed
- Lithuania OEL - TWA: Listed
- Portugal OEL - TWA: Listed
- Spain OEL - TWA: Listed
- Sweden OEL - TWAs: Listed


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.
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

Physical State: Film-coated tablets
Molecular Formula: Mixture
Color: White to off-white
Molecular Weight: Mixture

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)

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Sodium lauryl sulfate
Rat Oral LD50 1288 mg/kg

Azithromycin dihydrate
Mouse (F) Oral LD50 4000 mg/kg
Mouse (M) Oral LD50 3000 mg/kg
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 lauryl sulfate
Eye Irritation Rabbit Severe
11. TOXICOLOGICAL INFORMATION

Skin Irritation
Rabbit
Severe

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
6 Month(s)
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)

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)

Azithromycin dihydrate

Daphnia Magna
OECD
EC50
48 Hours
120 mg/L

Hyallela azteca
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)
12. ECOLOGICAL INFORMATION

Azithromycin dihydrate
Aspergillus niger (Fungus)  OECD MIC  > 1000 mg/L
Trichoderma viride (Fungus)  OECD MIC  > 1000 mg/L
Clostridium perfringens (Bacterium)  OECD MIC  2.0 mg/L
Bacillus subtilis (Bacterium)  OECD MIC 2.0 mg/L

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
Australia (AICS): Listed
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 232-679-6

Calcium phosphate dibasic, anhydrous
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Croskemellose sodium</td>
<td>Listed</td>
<td>Listed</td>
<td>231-826-1</td>
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<tr>
<td>Sodium lauryl sulfate</td>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Listed</td>
<td>205-788-1</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Listed</td>
<td>209-150-3</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

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

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End of Safety Data Sheet