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

Material Name: Azithromycin Extended Release for Oral Suspension

<table>
<thead>
<tr>
<th>Trade Name:</th>
<th>Zmax</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms:</td>
<td>Azithromycin Sustained Release Oral Powder for Suspension</td>
</tr>
<tr>
<td>Chemical Family:</td>
<td>Azalide</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Pharmaceutical product used as Antibiotic agent</td>
</tr>
</tbody>
</table>

**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
ChemSafe (24 hours): +44 (0)208 762 8322

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

Material Name: Azithromycin Extended Release for Oral Suspension

2. **HAZARDS IDENTIFICATION**

Appearance: White to off-white powder

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

Additional Hazard Information:

| Short Term: | May cause eye irritation (based on components) |
| Known Clinical Effects: | May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Serious allergic reactions, including anaphylaxis, have been reported. |
| EU Indication of danger: | Not classified |

**Australian Hazard Classification (NOHSC):** Non-Hazardous Substance. Non-Dangerous Goods.

Additional Information:

For a more detailed discussion of potential health hazards and toxicity see Section 11.

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>Hazardous 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>8.33</td>
</tr>
</tbody>
</table>
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>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>7631-86-9</td>
<td>EEC No. 418-260-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Spray dried artificial banana flavor</td>
<td>MIXTURE</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Spray dried artificial cherry flavor</td>
<td>MIXTURE</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium phosphate tribasic, anhydrous</td>
<td>7601-54-9</td>
<td>231-509-8</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Glycerin bhenenate</td>
<td>18641-57-1</td>
<td>242-471-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Hydroxypropyl cellulose</td>
<td>9004-64-2</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Magnesium hydroxide</td>
<td>1309-42-8</td>
<td>215-170-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Poloxamer 407</td>
<td>9003-11-6</td>
<td>Not listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Xanthan gum</td>
<td>11138-66-2</td>
<td>234-394-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</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: Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

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: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

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. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).

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/m^3

Magnesium hydroxide
Estonia OEL - TWA

Listed

Titanium dioxide
ACGIH Threshold Limit Value (TWA)

= 10 mg/m^3 TWA

Australia TWA

= 10 mg/m^3 TWA

Austria OEL - MAKs

Listed

Belgium OEL - TWA

Listed

Bulgaria OEL - TWA

Listed

Denmark OEL - TWA

Listed

Estonia OEL - TWA

Listed

France OEL - TWA

Listed

Germany (DFG) - MAK

= 1.5 mg/m^3 MAK

Greece OEL - TWA

Listed

Ireland OEL - TWAs

= 10 mg/m^3 TWA

= 4 mg/m^3 TWA

Latvia OEL - TWA

Listed

Lithuania OEL - TWA

Listed

Netherlands OEL - TWA

Listed

OSHA - Final PELS - TWAs:

= 15 mg/m^3 TWA total

Poland OEL - TWA

Listed

Portugal OEL - TWA

Listed

Romania OEL - TWA

Listed

Spain OEL - TWA

Listed

Sweden OEL - TWAs

= 5 mg/m^3 LLV

Colloidal silicon dioxide

Australia TWA

= 2 mg/m^3 TWA

Austria OEL - MAKs

Listed

Czech Republic OEL - TWA

Listed

Estonia OEL - TWA

Listed

Germany - TRGS 900 - TWAs

= 4 mg/m^3 TWA

Germany (DFG) - MAK

= 4 mg/m^3 MAK

Ireland OEL - TWAs

= 2.4 mg/m^3 TWA

= 6 mg/m^3 TWA

Latvia OEL - TWA

Listed

OSHA - Final PELs - Table Z-3 Mineral D:

(80)/(% SiO2) mg/m^3 TWA

= 20 mppcf TWA

Slovenia OEL - TWA

Listed

Sucrose

ACGIH Threshold Limit Value (TWA)

= 10 mg/m^3 TWA

Australia TWA

= 10 mg/m^3 TWA

Belgium OEL - TWA

Listed

Bulgaria OEL - TWA

Listed

Estonia OEL - TWA

Listed
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.

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: Powder
Molecular Formula: Mixture
Color: White to off-white
Molecular Weight: Mixture

Solubility: Soluble: Water
pH: 9.5 - 12.0 (reconstituted) (60 ml)

Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: Strong oxidizers, Acids
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)

Sucrose
Rat Oral LD50 29.7 g/kg

Glyceryl behenate
Rat Oral LD50 5 g/kg

Magnesium hydroxide
Rat Oral LD50 8500 mg/kg
Rat Intraperitoneal LD50 2780 mg/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Xanthan gum
Rat Oral LD50 > 5000 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)

Magnesium hydroxide
Eye Irritation Rabbit Moderate

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 & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Azithromycin dihydrate
Reproductive & Fertility Rat Oral 10 mg/kg/day NOEL Fertility
11. TOXICOLOGICAL INFORMATION

Prenatal & Postnatal Development  
Mouse  Oral 40 mg/kg/day  NOEL  Not Teratogenic  
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.

Colloidal silicon dioxide  
IARC:  Group 3 (Not Classifiable)

Titanium dioxide  
IARC:  Group 2B (Possibly Carcinogenic to Humans)  
OSHA:  Present

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.

**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 MIC2.0 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.

Sodium phosphate tribasic, anhydrous
  CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  Standard for the Uniform Scheduling for Drugs and Poisons:
  EU EINECS/ELINCS List
  
  = 2270 kg final RQ listed under Sodium phosphate, tribasic
  = 5000 lb final RQ listed under Sodium phosphate, tribasic
  Present
  Present
  Schedule 5
  231-509-8

Glyceryl behenate
  Australia (AICS):
  EU EINECS/ELINCS List
  
  Present
  242-471-7

Hydroxypropyl cellulose
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  EU EINECS/ELINCS List
  
  XU
  Present
  215-170-3

Magnesium hydroxide
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  EU EINECS/ELINCS List
  
  Present
  Present
  215-170-3

Poloxamer 407
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  EU EINECS/ELINCS List
  
  XU
  Present
  234-394-2

Xanthan gum
  Inventory - United States TSCA - Sect. 8(b)
  Australia (AICS):
  EU EINECS/ELINCS List
  
  XU
  Present
  234-394-2

Titanium dioxide
  Inventory - United States TSCA - Sect. 8(b)
  
  Present
16. OTHER INFORMATION

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 4 - First Aid Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

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

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet