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

Product Identifier

Material Name: Azithromycin dihydrate film coated tablets

Trade Name: ZITHROMAX; ZITROCIN; ULTREON; ZITROMAX; TRULIMAX; ZITROTEK; AZADOSE; AZITHROMYCINE; AZITHROMYCIN; AZITROCIN; AZITROMAX; ZETAMAX

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as antibiotic agent

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not required

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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

Hazardous
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</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>56</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>Starch, pregelatinized</td>
<td>9005-25-8</td>
<td>232-679-6</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>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not Listed</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.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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: Not determined

Advice for Fire-Fighters
Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe 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.

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

Calcium phosphate dibasic, anhydrous
Latvia OEL - TWA 10 mg/m³

Starch, pregelatinized
ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³

5 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:**
Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:**
Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:**
Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:**
Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Film-coated tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility:</td>
<td>No data available</td>
</tr>
<tr>
<td>pH:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient: (Method, pH, Endpoint, Value)</td>
<td></td>
</tr>
<tr>
<td>Calcium phosphate dibasic, anhydrous</td>
<td></td>
</tr>
</tbody>
</table>

No data available

**Color:** Pink or White to off-white

**Odor Threshold:** No data available.

**Molecular Weight:** Mixture

**Partition Coefficient:** (Method, pH, Endpoint, Value)
9. PHYSICAL AND CHEMICAL PROPERTIES

Magnesium stearate
No data available

Sodium lauryl sulfate
No data available

Azithromycin dihydrate
Measured 7 Log P 0.67

Crocarmellose sodium
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 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.

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

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

Sodium lauryl sulfate
11. TOXICOLOGICAL INFORMATION

**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:**

- **Sodium lauryl sulfate**
  - Eye Irritation: Rabbit, Moderate
  - Skin Irritation: Rabbit, Mild Moderate
  - Skin Sensitization - GPMT: Guinea Pig, Negative
  - Skin Sensitization - LLNA: Mouse, Negative

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

**Repeated Dose Toxicity:**

- **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:**

- **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:**

- **Sodium lauryl sulfate**
  - Bacterial Mutagenicity (Ames): *Salmonella*, Negative

- **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.

Toxicity:

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

Sodium lauryl sulfate
*Oncorhynchus mykiss* (Rainbow Trout)  LC50  96 Hours  3.6 mg/L

Azithromycin dihydrate
*Daphnia magna* (Water Flea)  OECD  EC50  48 Hours  120 mg/L
*Hyalella azteca* (Freshwater Amphipod)  OECD  LC50  96 Hours  > 120 mg/L
*Oncorhynchus mykiss* (Rainbow Trout)  OECD  LC50  96 Hours  > 84 mg/L
*Green Algae*  OECD  EC50  72 Hours  0.0037 mg/L
*Microcystis aeruginosa* (Blue-green Alga)  OECD  ErC50  96 Hours  0.0018 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: (Inoculum, Method, End Point, Result)

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

Azithromycin dihydrate
*Eisenia fetida* (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: No data available

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

Azithromycin dihydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Croskemellose sodium
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

Sodium lauryl sulfate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 6
- EU EINECS/ELINCS List: 205-788-1

Calcium phosphate dibasic, anhydrous
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
SAFETY DATA SHEET

Material Name: Azithromycin dihydrate film coated tablets

Revision date: 18-Jan-2019

Version: 5.1

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Substance/Preparation</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch, pregelatinized</td>
<td>231-826-1</td>
</tr>
</tbody>
</table>

| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65          | Not Listed  |
| Inventory - United States TSCA - Sect. 8(b) | Present |
| Australia (AICS):                 | Present     |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present |
| EU EINECS/ELINCS List             | 232-679-6   |

<table>
<thead>
<tr>
<th>Magnesium stearate</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td>209-150-3</td>
<td></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 8 - Exposure Controls / Personal Protection.

Revision date: 18-Jan-2019

Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this 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