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

Product Identifier

Material Name: Azithromycin dihydrate Powder for Oral Suspension
Trade Name: ZITHROMAX®, AZENIL; AZITROCIN; ZITROMAX; ZETAMAX; ZITROCIN; AZIMAX
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
Contact E-Mail: pfizer-MSDS@pfizer.com

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

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

Label Elements

Hazard Statements: May form combustible dust concentrations in air

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

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<th>Ingredient</th>
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<th>GHS Classification</th>
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<td>234-394-2</td>
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</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.

For the full text of the R phrases 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
- 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
- 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
- Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Minimize dust generation and accumulation. 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

Sucrose
- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
SAFETY DATA SHEET

Material Name: Azithromycin dihydrate Powder for Oral Suspension
Revision date: 25-Sep-2014
Version: 5.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls
Engineering Controls: Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

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
Odor: Cherry, vanilla and banana
Molecular Formula: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available.
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

FD & C Red No. 40
No data available
Hydroxypropyl cellulose
No data available
Sucrose
No data available
Xanthan gum
No data available
Spray dried artificial banana flavor
No data available
Spray dried artificial creme de vanilla flavor
No data available
Spray dried artificial cherry flavor
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

Sodium phosphate tribasic, anhydrous
No data available

Azithromycin dihydrate
Measured 7 Log P 0.67

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: May cause eye and skin irritation. Dust may cause irritation. Accidental ingestion may cause effects similar to those seen in clinical use. 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)

Sucrose
Rat Oral LD50 29.7 g/kg

Xanthan gum
Rat Oral LD50 > 5000 mg/kg
11. TOXICOLOGICAL INFORMATION

Azithromycin dihydrate

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)

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)

Sucrose
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)

Azithromycin dihydrate
*Daphnia magna* (Water Flea)  OECD  EC50  48 Hours  120 mg/L  
*Hyallela 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  ER50  96 Hours  0.0018 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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

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

Azithromycin dihydrate
*Eisenia fetida* (Earthworm)  TAD  NOEC  28 Days  1000 mg/kg

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

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.

Spray dried artificial creme de vanilla flavor
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

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

Spray dried artificial banana flavor
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Spray dried artificial cherry flavor
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Sodium phosphate tribasic, anhydrous
- CERCLA/SARA 313 Emission reporting: Not Listed
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - California Proposition 65: Not Listed
  - Inventory - United States TSCA - Sect. 8(b): Present
  - Australia (AICS): Present
  - EU EINECS/ELINCS List: 231-509-8
SAFETY DATA SHEET

Material Name: Azithromycin dihydrate Powder for Oral Suspension
Revision date: 25-Sep-2014

15. REGULATORY INFORMATION

FD & C Red No. 40

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Hydroxypropyl cellulose

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Xanthan gum

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Sucrose

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16. OTHER INFORMATION

Data Sources: 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 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Revision date: 25-Sep-2014

Prepared by: Product Stewardship Hazard Communication

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