



MATERIAL SAFETY DATA SHEET

Revision date: 28-Jun-2013

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

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Sandwich, Kent
CT13 9NJ
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Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Material Name: Azithromycin Extended Release for Oral Suspension

Trade Name: Zmax
Synonyms: Azithromycin Sustained Release Oral Powder for Suspension
Chemical Family: Azalide
Intended Use: Pharmaceutical product used as Antibiotic agent

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:

Note: 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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Azithromycin dihydrate	117772-70-0	Not Listed	Not Listed	8.33
Sucrose	57-50-1	200-334-9	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Spray dried artificial banana flavor	MIXTURE	Not Listed	Not Listed	*
Spray dried artificial cherry flavor	MIXTURE	Not Listed	Not Listed	*
Sodium phosphate tribasic, anhydrous	7601-54-9	231-509-8	Not Listed	*
Glyceryl behenate	18641-57-1	242-471-7	Not Listed	*
Magnesium hydroxide	1309-42-8	215-170-3	Not Listed	*
Poloxamer 407	9003-11-6	Not Listed	Not Listed	*
Xanthan gum	11138-66-2	234-394-2	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*
Hydroxypropyl cellulose	9004-64-2	Not Listed	Not Listed	*

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.

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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). 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.

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

Sucrose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Slovakia OEL - TWA	6 mg/m ³
Spain OEL - TWA	10 mg/m ³

Colloidal silicon dioxide

Australia TWA	2 mg/m ³
Austria OEL - MAKs	4 mg/m ³
	0.3 mg/m ³
Czech Republic OEL - TWA	0.1 mg/m ³
	4.0 mg/m ³
Estonia OEL - TWA	2 mg/m ³
Finland OEL - TWA	5 mg/m ³
Germany - TRGS 900 - TWAs	4 mg/m ³
Germany (DFG) - MAK	4 mg/m ³
Ireland OEL - TWAs	6 mg/m ³
	2.4 mg/m ³
Latvia OEL - TWA	1 mg/m ³
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
	Listed
Slovakia OEL - TWA	4.0 mg/m ³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³
Estonia OEL - TWA	5 mg/m ³
France OEL - TWA	10 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10.0 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

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.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

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

Color:

White to off-white

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solubility:

Soluble: Water

pH:

9.5 - 12.0 (reconstituted) (60 ml)

Polymerization:

Will not occur

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10. STABILITY AND REACTIVITY

Chemical 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)

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 Sub-tenon injection (eye) LD50 2780 mg/kg

Titanium dioxide

Rat Oral LD50 > 7500 mg/kg

Rat Subcutaneous LD50 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

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11. TOXICOLOGICAL INFORMATION

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
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: See below

Colloidal silicon dioxide

IARC: Group 3 (Not Classifiable)

Titanium dioxide

IARC: Group 2B (Possibly Carcinogenic to Humans)
OSHA: Listed

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 (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

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

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12. ECOLOGICAL INFORMATION

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

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

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.

Azithromycin dihydrate

California Proposition 65

Not Listed

Spray dried artificial banana flavor

California Proposition 65

Not Listed

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15. REGULATORY INFORMATION

Spray dried artificial cherry flavor California Proposition 65	Not Listed
Sodium phosphate tribasic, anhydrous CERCLA/SARA Hazardous Substances and their Reportable Quantities: California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List	5000 lb 2270 kg Not Listed Present Present 231-509-8
Glyceryl behenate California Proposition 65 Australia (AICS): EU EINECS/ELINCS List	Not Listed Present 242-471-7
Magnesium hydroxide California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List	Not Listed Present Present 215-170-3
Poloxamer 407 California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS):	Not Listed Present Present
Xanthan gum California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): EU EINECS/ELINCS List	Not Listed Present Present 234-394-2
Water California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List	Not Listed Present Present Present 231-791-2
Sucrose California Proposition 65 Inventory - United States TSCA - Sect. 8(b) Australia (AICS): REACH - Annex IV - Exemptions from the obligations of Register: EU EINECS/ELINCS List	Not Listed Present Present Present 200-334-9
Hydroxypropyl cellulose California Proposition 65	Not Listed

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15. REGULATORY INFORMATION

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Colloidal silicon dioxide	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-545-4
Titanium dioxide	
California Proposition 65	carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5

16. OTHER INFORMATION

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

Reasons for Revision: Updated Section 7 - Handling and Storage. Updated Section 10 - Stability and Reactivity.
Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

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

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