MATERIAL SAFETY DATA SHEET

SECTION 1 - CHEMICAL PRODUCT & COMPANY IDENTIFICATION

Pfizer Inc
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Hours of operation 24 hours

Trade names	**ZITHROMAX®**
Product name	**Zithromax®(Azithromycin dihydrate) for oral suspension, 1 g**
Synonyms	ZITHROMAX® single dose packet, 1 g
Chemical family	Azalide
Therapeutic use	Antibacterial
Description	White to off-white powder with a cherry-banana odor

SECTION 2 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	Amount
Azithromycin dihydrate*	117772-70-0	Trade secret
Sucrose*	57-50-1	Trade secret
Sodium phosphate tribasic, anhydrous	7601-54-9	Trade secret
Silicon dioxide, colloidal NF*	7631-86-9	Trade secret
Spray dried artificial banana flavor	Mixture	Trade secret
Spray dried artificial food cherry flavor	Not assigned	Trade secret

*Hazardous

Note: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

SECTION 3 - HAZARDS IDENTIFICATION

Signal word	**CAUTION!**
Statements of hazard	**MODERATELY SENSITIVE TO IGNITION**
Eye effects	May cause eye irritation.
Skin effects	May cause skin irritation.
Inhalation effects	Dust may cause irritation. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion effects	Accidental ingestion may cause effects similar to those seen in clinical use. See 'Known clinical effects and 'Other potential health effects', below.

SECTION 3 - HAZARDS IDENTIFICATION ... continued

Known clinical effects	May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain.
Other potential health effects	Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.
Additional data	For a more detailed discussion of potential health hazards and toxicity see Section 11.
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.

SECTION 4 - FIRST AID MEASURES

Eyes	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin	Remove clothing and wash affected skin with soap and water. If irritation occurs or persists, get medical attention.
Inhalation	Remove to fresh air. If discomfort persists, get medical attention.
Ingestion	Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 5 - FIRE FIGHTING MEASURES

Fire fighting instructions	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.
Extinguishing media	Use carbon dioxide, dry chemical, or water spray.
Hazardous combustion products	Emits toxic fumes of carbon monoxide, carbon dioxide and oxides of nitrogen
Flash point	Not applicable

SECTION 6 - ACCIDENTAL RELEASE MEASURES

General	Review Sections 3, 8 and 12 before proceeding with clean up.
Small spill	Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.

SECTION 6 - ACCIDENTAL RELEASE MEASURES ... continued

Large spill

Spills should be handled by vacuuming or wet mopping. Avoid generating airborne dust. Transfer all waste to a labeled container and move it to a secure holding area.

SECTION 7 - HANDLING AND STORAGE

General handling

Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Use adequate ventilation. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing.

Storage conditions

Store out of direct sunlight in a well ventilated area at room temperature.

Temperature range for storage

5-30°C (41-86°F)

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits

Compound	Issuer	Type	OEL
Azithromycin dihydrate	Pfizer	TWA-8 Hr	0.5 mg/m³
Sucrose	OSHA	TWA-8 Hr	5 mg/m³ (respirable fraction)
	OSHA	TWA-8 Hr	15 mg/m³ (total dust)
	ACGIH	TWA-8 Hr	10 mg/m³

Exposure information

See exposure limits for component (s) listed above.

Analytical method

Azithromycin: CAM-KSB-96-01; STP A132.3 (contact Pfizer for additional details).

Ventilation

Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab hood.

Eye protection

Safety glasses or goggles

Skin protection

Use protective clothing (lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Hand protection

Wear protective gloves

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.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form	Powder
Color	White to off-white
Odor	Cherry-banana
Taste	Cherry-banana
pH	No data available
Melting point	No data available
Density	No data available
Vapor pressure	No data available
Water solubility	No data available
Solvent solubility	No data available
Dust explosion risk	See below
Minimum ignition energy (mJ)	10-25

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable
Incompatibilities	Strong oxidizers
Hazardous polymerization	Will not occur
Explosive properties	This material may present a dust explosivity hazard and has moderate sensitivity to ignition.

SECTION 11 - TOXICOLOGY INFORMATION

Toxicology summary The information included in this section describes the potential hazards of the active ingredient.

Acute toxicity

Compound	Type	Route	Species	Result
Azithromycin dihydrate	LD_{50}	Oral	Rat	>2000 mg/kg
	LD_{50}	Oral	Mouse (F)	4000 mg/kg
	LD_{50}	Oral	Mouse (M)	3000 mg/kg

Eye Azithromycin may be slightly irritating to eyes, based on extrapolation of minimal and moderate irritation seen in intravenous and intramuscular irritation studies, respectively.

SECTION 11 - TOXICOLOGY INFORMATION ... continued

Skin	Azithromycin may be slightly irritating to skin, based on extrapolation of minimal and moderate irritation seen in intravenous and intramuscular irritation studies, respectively.
Inhalation	Not determined
Ingestion	See Acute toxicity table
Mutagenicity	No evidence of mutagenic activity in bacterial cells *in vitro* or in mammalian cells *in vivo*. No evidence of clastogenic activity *in vitro* or *in vivo*.
Subchronic effects	The oral toxicity of azithromycin dihydrate was evaluated in rats at doses up to 20 mg/kg and in dogs at doses up to 40 mg/kg for six months. Mild alterations in liver enzymes were noted in all dose groups in the rat during and after cessation of treatment. Phospholipidosis (intracellular phospholipid accumulation) has been observed in various organ systems in mice, rats, and dogs. This effect was reversible and its significance to humans is unknown.
Chronic effects/ carcinogenicity	No data available
Carcinogen status	Not listed as a carcinogen by IARC, NTP or US OSHA.
Reproductive effects	Decreased pregnancy rate was observed in a reproduction and fertility study in rats at oral (gavage) doses up to 20 mg/kg/day of azithromycin. No other drug-related effects were noted in dams or progeny.
Teratogenicity	No evidence of teratogenicity was observed for azithromycin in mice or rats at oral dose levels up to 40 mg/kg/day.
At increased risk from exposure	Individuals who have shown sensitivity to macrolide antibiotics (i.e., erythromycin).
Additional information	FDA PREGNANCY CATEGORY B

SECTION 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.
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.

SECTION 12 - ECOLOGICAL INFORMATION ... continued

Aquatic toxicity

Compound	Type	Species	Result
Azithromycin dihydrate	EC50/48h	Daphnia magna	120 mg/L
	LC50/96h	Hyallela azteca	>120 mg/L
	LC50/28 day	Lumbricus terrestris	>1000 mg/kg
	IC50	Activated sludge	269 mg/L
	MIC	Aspergillus niger	>1000 mg/L
	MIC	Trichoderma viride	>1000 mg/L
	MIC	Clostridium perfringens	2.0 mg/L
	MIC	Bacillus subtilis	2.0 mg/L
	MIC	Nostoc	0.4 mg/L

Partition coefficient LogP = 0.65 @ pH 7 and temperature 20°C (Azithromycin)

Degradability Half life <28 days (Aerobic Biodegredation- Water)

SECTION 13 - DISPOSAL INFORMATION

Disposal procedure Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

SECTION 14 - TRANSPORTATION INFORMATION

General shipping instructions Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

SECTION 15 - REGULATORY INFORMATION

EU Classification Not classified

EU Labelling None required

WHMIS Classification 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.

SECTION 16 - OTHER

Disclaimer **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 a warranty of any kind, expressed or implied.**