



MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF PRODUCT AND COMPANY

Pfizer Inc	Emergency telephone	1-866-531-8896
Pfizer Animal Health	Hours of operation	24 Hours
235 East 42nd Street	Telephone	1-800-366-5288
New York, NY 10017		

Trade names	ZENIQUIN[®] Film Coated Tablets
Product name	Marbofloxacin tablets
Chemical family	Fluoroquinolone
Therapeutic use	Antibacterial
Description	Beige-colored modified oval shaped tablets

SECTION 2 - COMPOSITION

<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Marbofloxacin*	115550-35-1	Proprietary
Microcrystalline cellulose*	9004-34-6	Proprietary
Hydroxypropyl methylcellulose	9004-65-3	Proprietary
Sodium starch glycolate	9063-38-1	Proprietary
Stearic acid*	57-11-4	Proprietary

*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	CONTAINS A SUBSTANCE WHICH MAY CAUSE EFFECTS TO CARTILAGE, LIVER, AND REPRODUCTIVE SYSTEM
Eye effects	Dust may cause irritation (based on animal data).
Skin effects	Not a skin irritant (based on animal data).
Inhalation effects	Dust may be hazardous. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8). See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.
Ingestion effects	See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.

SECTION 3 - HAZARDS IDENTIFICATION ... continued

Known clinical effects	Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Serious allergic reactions, including anaphylaxis, have been reported. Convulsions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones.
Other potential health effects	There is a risk of photosensitization within a few hours after excessive exposure to quinolones. If excessive exposure does occur, avoid direct sunlight and wash skin with soap and water. This compound may cause cartilage deterioration in knee joints and adverse reproductive effects (based on animal data).
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

Skin	Remove contaminated clothing and shoes. Wash skin with soap and water. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.
Eyes	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Inhalation	Not an expected route of exposure. In case of over exposure, move exposed person to fresh air. Refer to a physician if subject experiences difficulty breathing.
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

General hazard	Toxic or corrosive emissions may be given off in a fire. See Hazardous combustion products, below.
Fire fighting instructions	Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.
Extinguishing media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Flash point	Not applicable

SECTION 5 - FIRE FIGHTING MEASURES ... continued

Hazardous combustion products Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and fluorine-containing compounds.

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. Prevent discharge to drains.

Large spill Spills should be handled by vacuuming or wet mopping. Transfer all waste to a labeled container and move it to a secure holding area.

SECTION 7 - HANDLING AND STORAGE

General handling Keep away from heat. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Avoid generating airborne dust.

Storage conditions Keep in tightly closed containers or packages away from moisture and heat. Store out of direct sunlight in a well ventilated area at room temperature.

Temperature range for storage 15-30°C

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limits

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Marbofloxacin	Pfizer	TWA-8 Hr	0.2 mg/m ³
Microcrystalline cellulose	ACGIH	TWA-8 Hr	10 mg/m ³ (total dust)
	OSHA	TWA-8 Hr	5 mg/m ³ (respirable fraction)
	OSHA	TWA-8 Hr	15 mg/m ³ (total dust)
Stearic acid	ACGIH	TWA-8 Hr	10 mg/m ³ (as stearates)

Exposure information The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Measurement method Marbofloxacin: CAM-KAS-99-15; STPM 135.01 (Contact Pfizer for additional details)

Ventilation General room ventilation is adequate unless the process generates dust, mist or fumes.

Respiratory protection Not required for the normal use of this product. Use dust mask for dusty conditions.

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ... continued

Eye protection	Wear safety glasses or goggles if eye contact is possible.
Skin protection	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Hand protection	Not required for the normal use of this product. Wear protective gloves when working with large quantities.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Physical form	Film-coated tablets
Color	Beige
Molecular weight	Mixture
Molecular formula	Mixture
pH	Not applicable
Boiling point	Not applicable
Melting point	No data available
Density	Not applicable
Vapor pressure	Not applicable
Water solubility	No data available
Solvent solubility	No data available

SECTION 10 - STABILITY AND REACTIVITY

Reactivity	Stable
Conditions to avoid	Direct sunlight, conditions that might generate heat and dispersion as a dust cloud
Incompatibilities	None known
Hazardous decomposition products	No data available
Hazardous polymerization	Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

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

Acute toxicity

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Result</u>
Marbofloxacin	LD ₅₀	Oral	Rat	2720-3772 mg/kg
	LD ₅₀	Oral	Mouse	1781-1822 mg/kg

Eye May cause eye irritation (based on animal data)

Skin Not irritating (based on animal data)

Inhalation No data available

Ingestion See Acute toxicity table

Mutagenicity Weakly positive effects in the Ames test strain TA102 and gene mutation assays with yeast are typical of quinolone antimicrobials due to their mode of action.

Sensitization Skin sensitization and/or photosensitization (allergic response after UV exposure) of other quinolones have been demonstrated in guinea pigs, mice, and humans.

Subchronic effects Oral studies of up to 3-months duration have been conducted in dogs and rats. At the highest dose of 600 mg/kg in rats, findings included obstructive changes in the urinary tract with increased mortality, testicular atrophy and decreased weights of the testes and male accessory sex glands. Doses of 50 mg/kg or higher in rats caused changes in joint cartilage. In dogs, joint cartilage lesions were found at doses of 10 mg/kg/day and higher. All findings were considered to be typical for the fluoroquinolone class of antibacterials.

**Chronic effects/
carcinogenicity** Long-term toxicity studies to evaluate the carcinogenic potential of marbofloxacin were conducted in rats at dose levels up to 250 mg/kg/day and in mice at dose levels up to 600 mg/kg/day. Proliferation of bile ducts in the liver and effects on cartilaginous tissues were observed in rats at doses greater than 20 mg/kg/day.

Carcinogen status Not listed as a carcinogen by IARC, NTP or US OSHA.

Reproductive effects In a 2-generation reproduction safety study in rats, the highest dose of 500 mg/kg/day caused testicular effects with reduced fertility in males. Among pregnant females, effects at 500 mg/kg/day included reduced implantation rate, increased post-implantation loss, reduced litter size, increased pup mortality and reduced pup weight gains. These effects occur with other quinolone antimicrobials as well.

Teratogenicity No teratogenic effects were observed in oral studies in rats and rabbits.

SECTION 11 - TOXICOLOGY INFORMATION ... continued

At increased risk from exposure Individuals with a history of hypersensitivity to this material or members of the quinolone class of antimicrobials and those with known seizure disorders.

SECTION 12 - ECOLOGICAL INFORMATION

Environmental overview In the environment, the active ingredient in this formulation is expected to bind tightly to soil or sediment and degrade rapidly when exposed to sunlight. No information on aquatic toxicity is available.

Mobility, persistence, and degradability: The active ingredient in this formulation is expected to bind to soil, sediment, or with solids in a wastewater treatment facility and degrade rapidly when exposed to sunlight.

Bioaccumulation and toxicity: See the aquatic toxicity data for the active ingredient in the table, below.

Aquatic toxicity

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Result</u>
Marbofloxacin	LC50/48h	Daphnia magna	62.3mg/L (NOEC)

Log P (octanol/water partition coefficient) -0.835 at pH 7, 25°C (marbofloxacin)

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 Harmful
Toxic to Reproduction; Category 3

EU Labelling Xn

EU Label Pictogram(s)



SECTION 15 - REGULATORY INFORMATION ... continued

Risk phrases	R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed. R62 - Possible risk of impaired fertility.
Safety phrases	S22 - Do not breathe dust. S36 - Wear suitable protective clothing. S53 - Avoid exposure - obtain special instructions before use.
TSCA status	Not listed
SARA section 302	No
SARA section 313	No
California Proposition 65	Not listed
Canadian WHMIS	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.
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