SAFETY DATA SHEET

1. Identification

Product identifier	**ZENIQUIN**
Other means of identification	
Synonyms	Zeniquin® * Zeniquin Tablets * Zeniquin Film Coated Tablets * Marbofloxacin tablets
Recommended use	Veterinary product used as Antibacterial
Recommended restrictions	Not for human use

Manufacturer/Importer/Supplier/Distributor information

Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 1 (connective tissue, nervous system)
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	

Label elements

Signal word	Danger
Hazard statement	Suspected of damaging fertility or the unborn child. Causes damage to organs (connective tissue, nervous system) through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.

Supplemental information Danger of very serious irreversible effects. sensory/motor nerve injury (peripheral neuropathy) may occur.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Marbofloxacin		115550-35-1	***
Microcrystalline cellulose		9004-34-6	*
Stearic acid		57-11-4	*

Composition comments *** 25, 50, 100 or 200 mg per tablet
* Non-hazardous Ingredients
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

Inhalation Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. For breathing difficulties, oxygen may be necessary.

Skin contact Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. 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.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.

Ingestion Rinse mouth. Call a physician or poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Rash. (allergic skin rash); Difficulty in breathing. Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Conlvusions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones. The most common adverse reactions associated with the use of quinolones include gastrointestinal distress, such as nausea or diarrhea, and central nervous system (CNS) effects, including insomnia, dizziness, and seizures. sensory/motor nerve injury (peripheral neuropathy) may occur.

Indication of immediate medical attention and special treatment needed May cause central nervous system effects. Monitor respiratory, cardiac and central nervous system. Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. CAUTION! - Individuals with a history of hypersensitivity to this material or members of the quinolone class of antimicrobials and those with known seizure disorders.

5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Use water spray to cool unopened containers.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Avoid contact with eyes, skin, and clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Remove sources of ignition.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Do not taste or swallow. Avoid contact with eyes, skin, and clothing. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid prolonged exposure. Minimize dust generation and accumulation. When using, do not eat, drink or smoke. Wash thoroughly after handling. Wear appropriate personal protective equipment. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep away from heat and sources of ignition. Store in original tightly closed container. @ 15-30°C (59-86°F). Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children. Protect from moisture.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Zoetis

Components	Type	Value
Marbofloxacin (CAS 115550-35-1)	TWA	0.2 mg/m³

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3
Stearic acid (CAS 57-11-4)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values

No biological exposure limits noted for the ingredient(s).

Control banding approach

Not available.

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General room ventilation is adequate unless the process generates dust, mist or aerosols.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection	No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. 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.
Thermal hazards	Not applicable.
General hygiene considerations	Observe any medical surveillance requirements. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance	Film-coated tablets.
Physical state	Solid.
Form	Solid.
Color	Beige.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. Moisture.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard. May cause hypersensitivity reactions in susceptible individuals.

Skin contact Prolonged skin contact may cause temporary irritation. May cause hypersensitivity reactions in susceptible individuals. Photosensitivity may occur.

Stearic acid	Species: Rabbit Severity: Moderate
Marbofloxacin	Species: Rabbit Severity: Non-irritating
Microcrystalline cellulose	Species: Rabbit Severity: Non-irritating

Eye contact Direct contact with eyes may cause temporary irritation.

Stearic acid	Species: Rabbit Severity: Mild
Marbofloxacin	Species: Rabbit Severity: Minimal
	Species: Rabbit Severity: Non-irritating
Microcrystalline cellulose	Species: Rabbit Severity: Non-irritating

Ingestion Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Rash. (allergic skin rash); Difficulty in breathing. Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Conlvusions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones. The most common adverse reactions associated with the use of quinolones include gastrointestinal distress, such as nausea or diarrhea, and central nervous system (CNS) effects, including insomnia, dizziness, and seizures. sensory/motor nerve injury (peripheral neuropathy) may occur.

Information on toxicological effects

Acute toxicity Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Components	Species	Test Results
Marbofloxacin (CAS 115550-35-1)		
Acute		
Oral		
LD50	Mouse	1781 - 1822 mg/kg
	Rat	2720 - 3772 mg/kg
Chronic		
Oral		
NOAEL	Mouse	600 mg/kg/day, 106 weeks (Not carcinogenic)
NOEL	Rat	250 mg/kg/day, 104 weeks (Not carcinogenic)

Components	Species	Test Results
Subacute		
Oral		
NOAEL	Dog	< 11 mg/kg/day, 14 days (Target organs: Connective tissue)
	Rat	250 mg/kg/day, 4 weeks (Target organs: None identified)
Subchronic		
Oral		
NOAEL	Rat	4 mg/kg/day, 13 weeks (Target organs: Male reproductive system, Connective tissue)
Microcrystalline cellulose (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 5000 mg/kg
Stearic acid (CAS 57-11-4)		
Acute		
Dermal		
LD50	Rabbit	> 5000 mg/kg
Oral		
LD50	Rat	> 4640 mg/kg
		4.6 g/kg
Chronic		
Oral		
LOAEL	Rat	300 ppm, 30 weeks Adipose tissue
Subcutaneous		
LOAEL	Mouse	0.05 mg/kg/week, 52 weeks Tumors
NOAEL	Rat	0.5 mg/kg/week, 26 weeks Not carcinogenic

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Marbofloxacin	Species: Rabbit Severity: Non-irritating

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye Contact

Stearic acid	Species: Rabbit Severity: Mild
Marbofloxacin	Species: Rabbit Severity: Minimal
	Species: Rabbit Severity: Non-irritating
Microcrystalline cellulose	Species: Rabbit Severity: Non-irritating

Respiratory or skin sensitization

Respiratory sensitization Due to partial or complete lack of data the classification is not possible. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Skin sensitization Due to partial or complete lack of data the classification is not possible. Skin sensitization and/or photosensitization potential (allergic response after UV exposure) of other quinolones have been demonstrated in guinea pigs, mice, and humans.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Marbofloxacin	Bacterial Mutagenicity (Ames) Result: Positive Species: Salmonella
Stearic acid	In Vitro Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella
Marbofloxacin	In Vitro Chromosome Aberration Result: Negative Species: Human Lymphocytes
	In Vivo Micronucleus Result: Negative Species: Mouse Bone Marrow
	In Vivo Unscheduled DNA Synthesis Result: Negative Species: Rat Hepatocyte
Stearic acid	Unscheduled DNA Synthesis Result: Negative Species: E. coli

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Suspected of damaging fertility or the unborn child.

Developmental effects

Marbofloxacin	700 mg/kg/day Prenatal & Postnatal Development, Not Teratogenic, Maternal Toxicity Result: NOAEL Species: Rat Organ: Oral
	80 mg/kg/day Prenatal & Postnatal Development, Not Teratogenic, Maternal Toxicity Result: NOAEL Species: Rabbit Organ: Oral

Reproductivity

Marbofloxacin	10 mg/kg/day 2 Generation Reproductive Toxicity, Fertility, Embryotoxicity, Fetotoxicity Result: NOAEL Species: Rat Organ: Oral

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Causes damage to organs (connective tissue, nervous system) through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Chronic effects Danger of serious damage to health by prolonged exposure.

Further information Danger of very serious irreversible effects. sensory/motor nerve injury (peripheral neuropathy) may occur. This compound may cause cartilage deterioration in knee joints and adverse reproductive effects (based on animal data). Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components		Species	Test Results
Marbofloxacin (CAS 115550-35-1)			
	LC50	Daphnia magna (Water Flea)	62.3 mg/L, 48 Hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code None known.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 05-28-2017

Version # 01

Disclaimer Zoetis 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. The information in the sheet was written based on the best knowledge and experience currently available.

Revision information This document has undergone significant changes and should be reviewed in its entirety.