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 (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison & Drug Safety	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917 All Safety Data Sheets are available via our Zoetis Canada website at https://www.zoetis.ca/sds/sds.aspx
Supplier	Not available.

2. Hazard identification

Physical hazards	Not classified.	
Health hazards	Reproductive toxicity	Category 2
	Specific target organ toxicity following repeated exposure	Category 1 (connective tissue, nervous system)
Environmental 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/vapours/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.
Supplemental information	Danger of very serious irreversible effects. sensory/motor nerve injury (peripheral neuropathy) may occur.
Other hazards	None known.

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	*

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments

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

4. First-aid measures

Inhalation

Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTRE 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 centre 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

Exposed individuals may experience eye tearing, redness, and discomfort. Difficulty in breathing. Rash. Prolonged exposure may cause chronic effects. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. (allergic skin rash); Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Convulsions, 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. May cause sensory/motor nerve injury (peripheral neuropathy).

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Keep victim under observation. Monitor respiratory, cardiac and central nervous system. Symptoms may be delayed. May cause central nervous system effects.

General information

IF exposed or concerned: Get medical advice/attention. 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. For personal protection, see section 8 of the SDS. 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. Wear appropriate protective equipment and clothing during clean-up. Avoid the generation of dusts during clean-up. Avoid inhalation of dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. Avoid contact with eyes, skin, and clothing. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Methods and materials for containment and cleaning up

Remove sources of ignition. Ensure adequate ventilation. Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Shovel the material into waste container. Clean surface thoroughly to remove residual contamination.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. 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

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Minimise dust generation and accumulation. Do not taste or swallow. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Conditions for safe storage, including any incompatibilities

Store locked up. Protect from moisture. Keep away from heat and sources of ignition. Store in a well-ventilated place. Storage Temperature: 15-30°C (59-86°F). Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

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

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	
Stearic acid (CAS 57-11-4)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2), as amended

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

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Total dust.
Stearic acid (CAS 57-11-4)	TWA	3 mg/m3	Respirable.

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act), as amended

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

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act), as amended

Components	Type	Value	Form
Stearic acid (CAS 57-11-4)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.

Canada. New Brunswick OELs: Threshold Limit Values (TLVs) Based on the 1991 and 1997 ACGIH TLVs and BEIs Publication (New Brunswick Regulation 91-191)

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

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents), as amended

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	TWA	10 mg/m3	
Stearic acid (CAS 57-11-4)	TWA	3 mg/m3	Respirable fraction.

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety), as amended

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

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21), as amended

Components	Type	Value	Form
Microcrystalline cellulose (CAS 9004-34-6)	15 minute	20 mg/m3	Fiber.
Stearic acid (CAS 57-11-4)	15 minute	20 mg/m3	

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. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Other 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.

Colour Beige.

Odour Not available.

Melting point/freezing point Not available.

Boiling point or initial boiling point and boiling range	Not available.
Flammability	Not available.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Flash point	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
pH	Not available.
Kinematic viscosity	Not available.
Solubility	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water) (log value)	Not available.
Vapour pressure	Not available.
Density and/or relative density	Not available.
Vapour density	Not available.
Particle characteristics	Not available.
Other information	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

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	Moisture. Heat, flames and sparks. Contact with incompatible materials.
Incompatible materials	Strong oxidising agents. Fluorine.
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	Prolonged inhalation may be harmful. 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

Eye contact

Marbofloxacin	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. Difficulty in breathing. Exposure may cause temporary irritation, redness, or discomfort. Rash. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. (allergic skin rash); Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Convulsions, 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)
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

Components	Species	Test Results
Chronic		
Oral		
LOAEL	Rat	300 ppm, 30 weeks Adipose tissue
Subcutaneous		
LOAEL	Mouse	0.05 mg/kg/week, 52 weeks Tumours
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 sensitisation

Canada - Alberta OELs: Irritant

Microcrystalline cellulose (CAS 9004-34-6)	Irritant
Stearic acid (CAS 57-11-4)	Irritant

Respiratory sensitisation 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 sensitisation 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

Mutagenicity

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.

ACGIH Carcinogens

Stearic acid (CAS 57-11-4)	A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Stearic acid (CAS 57-11-4)	Not classifiable as a human carcinogen.

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 Prolonged inhalation may be harmful. Causes damage to organs through prolonged or repeated exposure. Danger of serious damage to health by prolonged exposure.

Further information Caution - Pharmaceutical agent. 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 Avoid release to the environment. 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.

Components		Species	Test Results
Marbofloxacin (CAS 115550-35-1)			
Aquatic			
Crustacea	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. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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.
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

TDG

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

Canadian regulations

This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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

Country(s) or region	Inventory name	On inventory (yes/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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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

Issue date 28-May-2017

Revision date 27-June-2024

Version No. 02

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.