


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	ENROFLOXACIN, USP (Not for Human Use)
PRODUCT CODE	2574
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Pharmaceutical Manufacturing
RESTRICTIONS ON USE	Veterinary

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 5) Acute Toxicity - Dermal (Category 5) Eye Irritation (Category 2A) Acute Aquatic Toxicity (Category 1)
PICTOGRAM	
SIGNAL WORD	Warning
HAZARD STATEMENT(S)	Causes serious eye irritation. May be harmful if swallowed. May be harmful if in contact with skin Very toxic to aquatic life.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	Repeated exposure may cause skin dryness or cracking.
PRECAUTIONARY STATEMENT(S)	Prevention Wear eye and face protection. Wash hands thoroughly after handling. Do not touch eyes. Avoid release to the environment.

HMIS CLASSIFICATION	Response	IF SWALLOWED: Get medical help. IF ON SKIN: Get medical help. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical help. COLLECT SPILLAGE		
	Storage	Not applicable		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
	Health Hazard	1	Flammability	0
	Reactivity	0	Personal Protection	E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	1-Cyclopropyl-7-(4-ethyl-1-piperazinyl)-6-fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid.
BOTANICAL NAME	Not applicable
SYNONYM	Not available
CHEMICAL FORMULA	C ₁₉ H ₂₂ FN ₃ O ₃
CHEMICAL FAMILY	Fluoroquinolone
CAS NUMBER	93106-60-6
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	359.39

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
ENROFLOXACIN	93106-60-6	618-911-2	100

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.
SYMPTOMS CAUSED BY EXPOSURE	Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL	Not applicable
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FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES
PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE
PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: ENROFLOXACIN CAS #: 93106-60-6

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
WEEL	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Add Country	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³.

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE

Solid

DESCRIPTION

Pale yellow to light yellow crystalline powder.

SOLUBILITY

Very slightly soluble in water at pH 7.

ODOR

Not available

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)

3.1 (25°C; pH 7)

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

(219 - 225)°C,
(426.2-437)°F

PARTICLE CHARACTERISTICS

Not available

OXIDIZING PROPERTY

Not available

pH

6.5 - 7.5 (1%)

RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.000001 kPa (25°C)	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidizing agents. Alkalis.
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 5000 Dermal: Rabbit: LD50: (mg/kg): > 2000 Inhalation: Rat: LC50: (mg/L/4hr): Not available
SKIN CORROSION/IRRITATION	Based on available data, the classification criteria are not met. Rabbit: Skin irritancy test. Result: Non-irritant.
SERIOUS EYE DAMAGE/EYE IRRITATION	Causes eye irritation. Rabbit: Eye irritancy test. Result: Moderately irritant; reversible in 7 days.
RESPIRATORY SENSITIZATION	Due to lack of data the classification is not possible. Guinea pig test Result: Negative.
SKIN SENSITIZATION	Based on available data, the classification criteria are not met.
GERM CELL MUTAGENICITY	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found. Mutagenicity: Chromosomal aberration test in Chinese hamster cells; Result: Positive. Forward mutation assay in Chinese hamster cells; Result: Equivocal. In vivo Chinese hamster bone marrow sister chromatid exchange assay; Result: Negative. In vivo mouse bone marrow micronucleus assay; Result: Negative. In vivo rat bone marrow chromosomal aberration assay; Result: Negative. Unscheduled DNA synthesis in rat hepatocytes; Result: Negative. Suspected mutagen: The Toolbox profiler Protein binding alerts for Chromosomal aberration by OASIS v1.1 gives an alert for mutagenicity; mutagen according to ISSSTY

CARCINOGENICITY
OSHA

ENROFLOXACIN is not listed.

NTP

ENROFLOXACIN is not listed.

IARC

ENROFLOXACIN is not evaluated.

California Proposition

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION

Based on available data, the classification criteria are not met.

Rat: 1000 mg/kg/day Carcinogenicity study; Test Duration (104 weeks); Result: No evidence of carcinogenicity noted.

Mouse: 3700 mg/kg/day Carcinogenicity study; Test Duration (104 weeks); Result: No evidence of carcinogenicity noted.

Suspected carcinogen: The Toolbox profiler Carcinogenicity (genotox and non genotox) alerts by ISS gives an alert for carcinogenicity

REPRODUCTIVE TOXICITY

Based on available data, the classification criteria are not met.

In a multi-center, prospective controlled trial in 400 women, therapeutic use of fluoroquinolones during embryogenesis was not associated with an increased risk of major malformations. In animal studies, fluoroquinolones have been shown to have a destructive effect on juvenile cartilage and weight-bearing joints.

Reproductivity:

Rat: 0 - 100 mg/kg/day 2-Generation reproductivity and development study, administered in feed. Result: No effect on fertility or reproductive performance.

Rat: 0 - 630 mg/kg/day 2-Generation reproductivity and development study, administered in feed. Result: Reproductive performance affected at high dose. Spermatic morphologic alterations in high-dose males. NOEL= 165 mg/kg/day

Rabbit: 0 - 75 mg/kg/day Reproductivity and development study; Result: Maternal toxicity and increased post-implantation losses at high dose.

Rat: 0 - 875 mg/kg/day Reproductivity and development study, administered by gavage during gestation. Result: Maternal toxicity; no teratogenicity. NOEL = 50 mg/kg/day

Suspected toxic for reproduction: The Toolbox profiler DART scheme v.1.0 gives an alert for toxicity to reproduction; DART database in the Toolbox reports that this substance as Known developmental potential

SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Based on available data, the classification criteria are not met.

SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE

Based on available data, the classification criteria are not met.

ASPIRATION HAZARDS

Based on available data, the classification criteria are not met.

**SIGNS AND SYMPTOMS OF
EXPOSURE**
ROUTES OF EXPOSURE:

Oral, Dermal, Inhalation, Eye contact

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Not available

DELAYED HEALTH EFFECT FROM EXPOSURE:

Fluoroquinolones: Tendon rupture. Tendonitis. Superinfection. Heart arrhythmias. Rhabdomyolysis. Liver damage. Central nervous system stimulation. Photosensitivity.

Symptoms related to the physical, chemical, and toxicological characteristics:

Fluoroquinolones: Nausea. Vomiting. Diarrhea. Altered taste. Dizziness. Drowsiness. Headache. Sleep disturbances. Slurred speech. Tremors. Restlessness. Convulsions. Skin rash. Joint tenderness or swelling.

Cross sensitivity:

Persons sensitive to fluoroquinolones or other chemically related quinolone derivatives may be sensitive to this material also.

Medical conditions aggravated by exposure:

Central nervous system disorders.

POTENTIAL HEALTH EFFECTS

Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion May be harmful if swallowed.

Skin May be harmful if absorbed through skin. May cause skin irritation.

Eyes Causes serious eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY

EC50: 48 Hr: Crustacea: *Penaeus vannamei*: (mg/L): 0.0143

LC50: 96 Hr: Fish: (mg/L): 10

EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

**PERSISTENCE AND
DEGRADABILITY**

Nonreadily biodegradable*

BIOACCUMULATIVE POTENTIAL

LogPow: 3.1 (25°C; pH 7)

MOBILITY IN SOIL

Very slightly soluble in water at pH 7.

Water solubility: 3400 mg/L (25°C)

Henry's Law Constant: 1.50E-18 atm-m³/mole (25°C)

OTHER ADVERSE EFFECTS

Not available

NOTES

This product is not intended to be released into the environment

*Danish QSAR database

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

UN NUMBER 3077
 CLASS 9
 PACKING GROUP III

AUSTRALIA

HAZCHEM 2Z

EU

TRANSPORT IN BULK ACCORDING
 TO ANNEX II OF MARPOL 73/78
 AND THE IBC CODE Not Listed

ENVIRONMENTAL HAZARDS Not available
 SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
ENROFLOXACIN, 93106-60-6	N/L	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
ENROFLOXACIN, 93106-60-6	N/L	Listed as Schedule 4	N/L	Listed	N/L	N/L

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
ENROFLOXACIN, 93106-60-6	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT Not applicable

SECTION 16: OTHER INFORMATION

REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

02/2023

SUPERSEDES

05/2021

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.