


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	CIPROFLOXACIN HYDROCHLORIDE, USP
PRODUCT CODE	0534
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	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 5) Acute Aquatic Toxicity (Category 3) Eye Irritation (Category 2A)
PICTOGRAM	
SIGNAL WORD	Warning
HAZARD STATEMENT(S)	Harmful to aquatic life. May be harmful if swallowed Causes serious eye irritation.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS PRECAUTIONARY STATEMENT(S)	Repeated exposure may cause skin dryness or cracking. Prevention Avoid release to the environment. Wash thoroughly after handling. Wear eye protection/face protection. Response 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 advice/attention. IF SWALLOWED: Get medical help.

HMIS CLASSIFICATION	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-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid, monohydrochloride, monohydrate.								
BOTANICAL NAME	Not applicable								
SYNONYM	Not applicable								
CHEMICAL FORMULA	C ₁₇ H ₁₈ FN ₃ O ₃ ·HCl·H ₂ O								
CHEMICAL FAMILY	Fluoroquinolone								
CAS NUMBER	86393-32-0								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	385.82								
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>CIPROFLOXACIN HCl (monohydrate)</td> <td>86393-32-0</td> <td>617-845-1</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	CIPROFLOXACIN HCl (monohydrate)	86393-32-0	617-845-1	100
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CIPROFLOXACIN HCl (monohydrate)	86393-32-0	617-845-1	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
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.

Store at 25°C, excursions permitted between 15° and 30°C.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: CIPROFLOXACIN HCl (monohydrate) CAS #: 86393-32-0

	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

Faintly yellowish to light yellow crystals, slightly hygroscopic.

SOLUBILITY

Sparingly soluble in water; slightly soluble in acetic acid and in methanol; very slightly soluble in dehydrated alcohol; practically insoluble in acetone, in acetonitrile, in ethyl acetate, in hexane, and in methylene chloride.

ODOR

Odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

(318 - 320)°C,
(604.4-608)°F

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)

0.025 (20°C)

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

(318 - 320)°C,
(604.4-608)°F
(decomposes)

PARTICLE CHARACTERISTICS

Not available

OXIDIZING PROPERTY

Not available

pH

3 - 4.5 (2.5%)

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

Not available

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 oxidants

**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): > 2000
 Dermal: Rabbit LD50: (mg/kg): Not available
 Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

 Based on available data, the classification criteria are not met.
 Local effects
 Skin irritancy test
 Result: Non-irritating.
 Species: Rabbit

**SERIOUS EYE DAMAGE/EYE
IRRITATION**

 pH 3.5 - 4.5 (2.5%) Causes serious eye irritation
 Local effects
 Eye irritancy test
 Result: Severely irritating.
 Species: Rabbit

RESPIRATORY SENSITIZATION

Due to lack of data the classification is not possible.

SKIN SENSITIZATION

 Due to lack of data the classification is not possible.
 Sensitization: There have been reports of hypersensitivity and anaphylactic reactions following therapeutic use of fluoroquinolones.

GERM CELL MUTAGENICITY

 Based on available data, the classification criteria are not met.
 Although positive results were obtained in two of eight in vitro studies, negative results were obtained in the in vivo rat hepatocyte DNA repair assay, micronucleus test in mice, and the dominant lethal test in mice.

CARCINOGENICITY

OSHA	CIPROFLOXACIN HYDROCHLORIDE is not listed.
NTP	CIPROFLOXACIN HYDROCHLORIDE is not listed.
IARC	CIPROFLOXACIN HYDROCHLORIDE is not evaluated.

ADDITIONAL CARCINOGENICITY INFORMATION
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.

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

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. In animal studies, the base of this material did not impair fertility or cause adverse reproductive effects.

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. Peripheral neuropathy.

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, numbness or tingling of hands or feet. Swelling.

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.

NOTES
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, numbness or tingling of hands or feet. 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:

Fluoroquinolones: Myasthenia gravis. History of tendonitis or tendon rupture. Bradycardia. QTc-interval prolongation. Hypokalemia or hypomagnesemia. Impaired liver or kidney function. History of seizures. Central nervous system disorders. Blood disorders. Photosensitivity disorders.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY	EC50: 48 Hr: Crustacea: (mg/L): 176 LC50: 96 Hr: Fish: (mg/L): >100 EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): >= 100
PERSISTENCE AND DEGRADABILITY	Not available
BIOACCUMULATIVE POTENTIAL	Log Pow: 0.025
MOBILITY IN SOIL	Sparingly soluble in water
OTHER ADVERSE EFFECTS	Contains a substance which causes risk of hazardous effects to the environment. This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS

DISPOSAL METHODS	Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
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SECTION 14: TRANSPORT INFORMATION

UN PROPER SHIPPING NAME	Not dangerous good
UN NUMBER	Not applicable
CLASS	Not applicable
PACKING GROUP	Not applicable

AUSTRALIA HAZCHEM	Not applicable
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EU TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE	Not listed
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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	Appendix B	Pennsylvania	Right-to-know New Jersey	Massachusetts	California Prop 65
CIPROFLOXACIN HCl, 86393-32-0	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
CIPROFLOXACIN HCl, 86393-32-0	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
CIPROFLOXACIN HCl, 86393-32-0	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
ABBREVIATIONS AND ACRONYMS

Available upon request

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

04/2021

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.