SAFETY DATA SHEET

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 661 Route 3, Unit C, Plattsburgh, NY, 12901 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 **MEDISCA Pharmaceutique Inc.** Tel.: 1.800.665.6334 | Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 **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	Manufacturing and Compounding
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	Repeated exposure may cause skin dryness or cracking.
PRECAUTIONARY STATEMENT(S)	**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.
	Storage	Not applicable
	Disposal	Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION

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	$C_{17}H_{18}FN_3O_3 \cdot HCl \cdot H_2O$
CHEMICAL FAMILY	Fluoroquinolone
CAS NUMBER	86393-32-0
ALTERNATE CAS NUMBER	Not applicable
MOLECULAR WEIGHT	385.82

COMPOSITION

CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT
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, CO_2 or water spray. **Large fire:** dry chemical, CO_2, 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/m³	ppm	mg/m³				
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, slighlty 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
POSSIBLITY 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.
	California Proposition 65	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.	

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.

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

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 Part 372.65	EPA 40 CFR Part 355 Appendix A	EPA 40 CFR Part 355 Appendix B	Right-to-know Pennsylvania	Right-to-know New Jersey	Right-to-know 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 Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemcials
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

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** – Instituto 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.