SAFETY DATA SHEET

Manufacturer: FDC Limited
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1. IDENTIFICATION

Product Name: Ciprofloxacin Ophthalmic solution USP 0.3% w/v

Recommended use: Pharmaceutical

2. HAZARD(S) IDENTIFICATION

Appearance: Clear, colorless solution

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.
Known Clinical Effects: Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. 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. Convulsions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION

CHEMICAL NAME	CAS NO.	SYNONYMS	CHEMICAL FORMULA	MOLECULAR WEIGHT	PERCENT (BY WEIGHT)
3-Quinolinecarboxylic acid, 1-cyclopropyl-6-fluoro-1,4-dihydro-4-oxo-7-(1-piperazinyl)-,monohydrochloride,dihydrate	85721-33-1	Ciprofloxacin Hydrochloride Dihydrate;Cyprofloxacin HCl	$C_{17}H_{18}FN_3O_3.HCl.2H_2O$	385.8	0.3%

The formula also contains:
Benzalkonium Chloride 0.006 % as a preservative, Edetate Disodium, Sodium acetate, acetic acid, Mannitol; Hydrochloric Acid and/or Sodium Hydroxide added to adjust pH (Approx 4.5), and Water for Injection.

4. FIRST AID MEASURES

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: Nausea or vomiting; mild diarrhea; abdominal pain; dizziness; blurred vision; drowsiness; pounding in the ears; slow or fast heartbeat; headache; nervousness or restlessness; increased sensitivity of skin to sunlight; skin rash; bloating or

swelling of face, arms, hands, lower legs, or feet; tingling of hands or feet; possible allergic reaction to material if inhaled, ingested or in contact with skin.

Medical Conditions Aggravated by Exposure: Hypersensitivity to the material; tendinitis; cerebral arteriosclerosis; epilepsy; kidney function impairment; persons sensitive to fluoroquinolones or other chemically related quinolone derivatives may be sensitive to this material also.

Notes to Physician: Treat supportively and symptomatically.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides, nitrogen Oxides, hydrogen chloride and hydrogen fluoride.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment/ Precautions for Fire-fighters: Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store away from acids, bases and oxidizing agents.

Specific End Use: Pharmaceuticals.

8. EXPOSURE CONTROL AND PERSONAL PROTECTION

Occupational Exposure Guidelines: Common or Chemical Name	**Employee Exposure Limits**
Ciprofloxacin Hydrochloride Dihydrate	No data available

Engineering Controls:
Engineering controls should be used as the primary means to control exposures.

Respiratory Protection:
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection:
Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Protective laboratory coat, apron, or disposable garment

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Solution

Color: Clear, colorless solution

Molecular Formula: Mixture

Molecular Weight: Mixture

Mixture Solubility: Soluble: Water

pH: 3.5-5.5

10. STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.

Incompatible Materials: Strong oxidizing agents, acids and bases.

Hazardous Decomposition Products: No data available.

11. TOXICLOLOGICAL INFORMATION

Information on the Likely Routes of Exposure:

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

Ingestion: May be harmful if ingested. May cause irritation.

Skin Contact: May be harmful if absorbed through the skin. May cause irritation.

Eye Contact: May be harmful in contact with eyes. May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Ciprofloxacin HCl	Rat	Oral	LD_{50}	5000 mg/kg
Ciprofloxacin HCl	Mouse	Oral	LD_{50}	5000 mg/kg
Ciprofloxacin HCl	Monkey	Oral	LD_{50}	5000 mg/kg

Acute Toxicity – Dermal: No data available.

Acute Toxicity – Inhalation: No data available.

Corrosivity: No data available.

Dermal Irritation: No data available.

Eye Irritation: No data available.

Sensitization: No data available.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: No data available.

Reproductive Effects: No data available.

Carcinogenicity: No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

Aquatic:

Compound	Species	Test Type	Dose
Ciprofloxacin HCl	Daphnia magna	EC_{50}	176 mg/l (24 Hours)
Ciprofloxacin HCl	Zebra barbel	LC_{50}	1000 mg/l (96 Hours)

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Mobility in Environment: No data available.

Other Adverse Effects: No data available

13. DISPOSAL CONSIDERATION

Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

UN Number: Not applicable.

UN Proper Shipping Name: Not applicable.

Transport Hazard Class (es): Not applicable.

Packing Group: Not applicable.

Department of Transportation: Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

15. REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations

EPA Designations: RCRA Hazardous Waste (40 CFR 261.33) Not Listed

FDA Designations: Prescription only medication National Drug Code
69315-308-10 (10mL)
69315-308-05 (5mL)
69315-308-02 (2.5mL)

OSHA Designations: (29CFR1910.1000, Table Z) Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting

RNIA PROPOSITION 65: Not Listed

16. OTHER INFORMATION

Not made with natural rubber latex.

NFPA Rating:
Health: 0
Flammability: 0
Reactivity: 0

HMIS Classification:
Health: 2
Flammability: 0
Physical Hazard: 0