

## Ciprofloxacin Ophthalmic Solution, USP 0.3%

### Section 1: Identification

**GHS Product Identifier:**Ciprofloxacin Ophthalmic Solution

USP 0.3%

**Formula:**C17H18FN3O3 • HCl • H2O

**CAS Number:**N/A

**Therapeutic Category:** Anti-infective (Antibacterial)

**Chemical Name:**Ciprofloxacin Hydrochloride

**Manufacturer Name, Address and Phone Number:**

Indoco Remedies Limited

Postal Address: L-32, 33 & 34, Verna Industrial Area, Verna,

Goa – 403 722, India.

**Distributor Name, Address and Phone Number:**

Rising Pharmaceuticals, Inc.

3 Pearl Court, Allendale, NJ 07401

1-800-521-5340

**Emergency Phone Number – Adverse Reactions/Product**

**Complaints/Product Inquiries:**

1-866-562-4597

**Recommended Use:**See product insert.

**Restrictions on Use:**See product insert.

### Section 2: Hazard(s) Identification

**Classification of the substance/mixture and any national or regional information:**Not hazardous

**Label elements:**

- **Signal word** –None
- **Hazard statement** –None
- **Hazard symbol** – None

**Precautionary statements:**N/A

**Other hazards:** While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

### Section 3: Composition/Information on Ingredients

**Substance:**

- **Chemical identity** –Ciprofloxacin hydrochloride

- **Common name, synonyms, etc.** –Ciprofloxacin hydrochloride
- **CAS number** –Not available
- **EC number** –Not available
- **Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance** –Not available

**Mixture:**

- **Chemical identity and concentration or concentration ranges of all ingredients which are hazardous within the meaning of the GHS and are present above their cutoff levels** – No data available

**Trade Secret Claim(s):**No data available

### Section 4: First-Aid Measures

**Description of necessary measures:**

- **General** – Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive medical attention. If person is not breathing give artificial respiration, if breathing is difficult give oxygen. Obtain medical attention.
- **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
- **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.
- **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.

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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

- **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

### **Most important symptoms/effects, acute and delayed:**

Not available

### **Indication of immediate medical attention and special treatment needed, if necessary:**

Not available

### **Section 5: Fire-Fighting Measures**

**Suitable Extinguishing Media:** Use water, carbon dioxide, dry chemical or foam as necessary

**Unsuitable Extinguishing Media:** Not determined.

**Specific hazards arising from the chemical:** Formulation does not contain any hazardous ingredients

**Special protective equipment and precautions for firefighters:** Wear self-contained breathing apparatus and full and protective gear.

### **Section 6: Accidental Release Measures**

**Personal precautions, protective equipment and emergency procedures:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices

**Environmental precautions:** Not available.

**Methods and materials for containment and cleaning up:** Reference Section 13.

### **Section 7: Handling & 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 incompatible materials:** Store according to label and/or product insert information. Store away from oxidizing agents and acids  
**Storage Temperature Conditions:** Store at 25 °C (77°F); excursion permitted to 15° to 30° (59 to 86°F). Protect from light.

### **Section 8: Exposure Controls/Personal Protection**

**Control Parameters:** Not available

- **OSHA's Permissible Exposure Limits (PELs):**
- **Threshold Limit Values (TLVs):**

**Appropriate Engineering Controls:** Not available

**Individual protection measures, such as Personal Protection Equipment (PPE):**

- **Eye and face protection**– Not required for the normal use of this product. 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
- **Skin protection**– Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities
- **Hand protection** – ot required for the normal use of this product. 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
- **Body protection** – Not available.
- **Other protection**– Not available.
- **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).
- **Thermal hazards** – Not available.

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### Section 9: Physical & Chemical Properties

#### Appearance:

- **Dosage Form** – Ophthalmic solution
- **Color** –Light yellow to Yellow
- **Physical state** – Liquid

**Odor:**No data available

**Odor Threshold:**No data available

**pH:**3.5-5.5

**Melting point/Freezing point:** No data available

**Initial boiling point and boiling range:**No data available

**Flash point:**No data available

**Evaporation rate:**No data available

**Flammability (solid,gas):**No data available

**Upper/lower flammability or explosive limits:**No data available

**Vapor pressure:**No data available

**Vapor density:**No data available

**Relative density:**No data available

**Solubility(ies):**No data available

**Partition coefficient: n-octanol/water**No data available

**Autoignition temperature:**No data available

**Decomposition temperature:**No data available

### Section 10: Stability & Reactivity

**Reactivity:**No data available

**Chemical stability:** Stable under recommended storage conditions

**Possibility of hazardous reactions:** No data available.

**Conditions to avoid:** No data available.

**Incompatible materials:** No data available.

**Hazardous decomposition products:**No data available.

### Section 11: Toxicological Information

**Information on toxicological (health) effects:**Not available.

#### Information on likely route of exposure:

- **Inhalation** – Avoid inhalation. May be harmful if inhaled. Material is irritating to mucous membranes and upper respiratory tract
- **Ingestion** – Harmful if swallowed.
- **Skin contact** – May be harmful if absorbed through skin. Causes skin irritation

- **Eye contact** – Not irritating
- Symptoms related to the physical, chemical and toxicological characteristics:**No data available.

#### Delayed and immediate effects and also chronic effects from short- and long-term exposure:

- **Serious Eye Damage / Irritation** – No data available
- **Skin Corrosion / Irritation** – No data available
- **Respiratory or Skin Sensitization** – No data available
- **Reproductive Effects** – No data available
- **Mutagenic Effects** – No data available
- **LD<sub>50</sub> / (Oral)** – No data available
- **Developmental Effects** – No data available
- **Specific target organ toxicity (STOT)-Single Exposure** – No data available
- **STOT-Repeated Exposure** – No data available
- **Aspiration Hazard** – No data available
- **Carcinogenicity** – No data available
- **Further Information** –No data available

**Numerical measures of toxicity, such as acute toxicity estimates:**No data available

### Section 12: Ecological Information

**Ecotoxicity:**No data available

**Persistence and degradability:** No data available

**Bioaccumulative potential:**No data available

**Mobility in soil:**No data available

**Other adverse effects:** No data available

### Section 13: Disposal Considerations

**Waste treatment methods:**Dispose of all waste in accordance with Federal, State and Local regulations

- **Waste Disposal Method** – See above.
- **Contaminated packaging** –See above.

### Section 14: Transport Information

**Marine Pollutant (Yes/No):** No

**Air Transport (ICAO / IATA):**N/A

UN/ID No –N/A

UN Proper Shipping Name –N/A

Transport Hazard Class(es) – N/A

Packing Group – N/A

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Label Requirements – N/A

**Sea Transport (IMDG):** Not regulated as a hazardous material

UN/ID No –N/A

UN Proper Shipping Name –N/A

Transport Hazard Class(es) – N/A

Packing Group – N/A

Label Requirements – N/A

**Land Transport (DOT):** Not regulated as a hazardous material

UN/ID No –N/A

UN Proper Shipping Name –N/A

Transport Hazard Class(es) – N/A

Packing Group – N/A

Label Requirements – N/A

**Special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises:**

No data available

### **Section 15: Regulatory Information**

**NDC Number(s):**

16571-120-25 (2.5 mL)

16571-120-50 (5.0 mL)

### **Section 16: Other Information**

**Issue Date:** April 2016

**Version No.:** 01

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– End of SDS –