

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

| | | |
|------------------------------------|---|---|
| Product Name | : | Ofloxacin Otic Solution, 0.3% |
| Chemical Family | : | Fluoroquinolone |
| Synonyms | : | (±)-9-fluoro-2,3- dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido [1,2,3-de]-1,4-benzoxazine-6-carboxylic acid |
| Manufacturer or supplier's details | | Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA. |
| Emergency Telephone Number | : | +91-4467901901/02/03 |

Recommended use of the chemical and restrictions on use

| | | |
|---------------------|---|---|
| Recommended use | : | Ofloxacin Otic Solution is indicated for the treatment of infections such as otitis externa, chronic suppurative otitis media and acute otitis media caused by susceptible bacteria |
| Restrictions on use | : | Not applicable |

SECTION 2: HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

| | | |
|--------------------------|---|--|
| GHS Classification | : | Eye Mild Irritation 2B |
| Label elements | | |
| Hazard statements | : | May cause eye irritation |
| Precautionary statements | | |
| Prevention | : | Use personal protective equipment as required. Wash thoroughly after handling. |
| 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 |
| Storage/Disposal | : | Keep tightly closed. Store at room temperature 1530°C (59-86°F), to maintain product integrity. use before expiration date marked on carton and/or container. Protect from light. |
| Other Hazards | : | No data available |

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS# | Ingredient Percent |
|-----------------------|-------------|---------------------------|
| Benzalkonium Chloride | 63449-41-2 | 0.0025% |
| Hydrochloric acid | 7647-01-0 | <1% |
| Ofloxacin | 82419-36-1 | 0.3% |
| Sodium chloride | 7647-14-5 | 0.9% |
| Water for Injection | 7732-18-5 | Balance |

Note: Hydrochloric Acid (CAS:7647010, EINECS:2315957) and/or Sodium Hydroxide (CAS# 131073 2, EINECS: 2151855) may be added to adjust the pH.

SECTION 4 : FIRST AID MEASURES

- Inhalation : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.
- Skin : No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.
- Eye : For accidental and non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention if eye irritation persists.
- Ingestion : No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

Most important symptoms and effects, both acute and delayed

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones, including ofloxacin. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema) airway obstruction, dyspnea, urticaria, and itching. A rare occurrence of StevensJohnson syndrome, which progressed to toxic epidermal necrolysis, has been reported in a patient who was receiving topical ophthalmic ofloxacin. If an allergic reaction to ofloxacin occurs, discontinue the drug. Serious acute hypersensitivity reactions may require immediate emergency

Indication of any immediate medical attention and special treatment needed : treatment. Oxygen and airway management, including intubation should be administered as clinically indicated

Notes to Physician : Additional details are available on the product package insert or the Physicians Desk Reference.

SECTION 5 :FIRE FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media : Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media : No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards : None known - product is not flammable or combustible.

Hazardous Combustion Products : No data available

Advice for firefighters : As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

SECTION 6 :ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personnel Precautions : No special controls or personal protection required under conditions of intended use.

Emergency Procedures : In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8

Environmental Precautions : No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental Precautions : No data available

Methods and material for containment and cleaning up

Containment/Clean-up Measures : Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal.

SECTION 7 : HANDLING and STORAGE

Precautions of safe handling

Handling : No special handling is required. Refer to Section 8. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage : Keep tightly closed. Store at room temperature 15 – 30° (59-86°F) to maintain product integrity. Use before expiration date marked on carton and/or container. Protect from light.

SECTION 8 : EXPOSURE CONTROLS, PERSONAL PROTECTION

Control Parameters

Exposure Limits/Guidelines : Refer to the occupational exposure limits / guidelines for the individual product components.

| Exposure Limits/Guidelines | | | | | |
|-------------------------------|----------|---------------|---|--|--|
| | Results | ACGIH | Canada Quebec | NIOSH | OSHA |
| Hydrochloric acid (7647-01-0) | Ceilings | 2 ppm Ceiling | 5 ppm Ceiling ; 7.5 mg/m ³ Ceiling | 5 ppm Ceiling ; 7mg/m ³ Ceiling | 5 ppm Ceiling ; 7mg/m ³ Ceiling |

Exposure Control Notations : Hydrochloric acid (7647010): Carcinogens: (A4 - Not Classifiable as a Human Carcinogen)

Exposure controls

Engineering Measures/Controls : Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment

Respiratory : No respiratory protection required during normal handling
Eye/Face : Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn
Skin/Body : No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.
Hands : Gloves are not required under normal handling conditions.
Environmental Exposure Controls : No data available

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Material Description

Physical form : Liquid
Color : Greenish yellow
Odor Threshold : Not relevant
Appearance/Description : Clear, greenish yellow aqueous solution.
Odor : No odor.

General Properties

Boiling Point : No data available
Melting Point : Not relevant
pH : 6 to 7
Density : 0.95 to 1.05 g/mL
Viscosity : No data available
Specific Gravity/Relative Density : = 1.005
Water solubility : No data available
Decomposition Temperature : No data available

Volatility

Vapor Pressure : Not relevant
Vapor Density : Not relevant

| | |
|-------------------------------------|---------------------|
| Evaporation Rate | : No data available |
| Flammability | |
| Flash Point | : Not relevant |
| UEL | : Not relevant |
| LEL | : Not relevant |
| Autoignition | : Not relevant |
| Environmental | |
| Octanol/Water Partition coefficient | : No data available |

SECTION 10 : Stability and Reactivity

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|------------------------------------|---|
| Reactivity | : No dangerous reactions known. |
| Chemical stability | : Stable under normal temperatures and pressures. |
| Possibility of hazardous reactions | : No data available |
| Conditions to avoid | : Extreme heat or cold. Do not freeze. |
| Incompatible materials | : None. |
| Hazardous decomposition products | : None expected. |

SECTION 11 : TOXICOLOGICAL INFORMATION

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|--------------------------------------|---|
| GHS Properties | Classification |
| Acute toxicity | UN GHS• Classification criteria not met |
| Aspiration Hazard | UN GHS• Classification criteria not met |
| Carcinogenicity | UN GHS• Classification criteria not met |
| Germ Cell Mutagenicity | UN GHS• Classification criteria not met |
| Skin corrosion/Irritation | UN GHS• Classification criteria not met |
| Skin sensitization | UN GHS• Classification criteria not met |
| STOTRE | UN GHS• Classification criteria not met |
| STOTSE | UN GHS• Classification criteria not met |
| Toxicity for Reproduction | UN GHS• Classification criteria not met |
| Respiratory sensitization | UN GHS• Classification criteria not met |
| Serious eye damage/Irritation | UN GHS• Eye Mild Irritation 2B |

Potential Health Effects

Inhalation

Acute (Immediate) Under normal conditions of use, no health effects are expected.

Chronic (Delayed) Under normal conditions of use, no health effects are expected.

Skin

Acute (Immediate) Not expected to cause skin irritation.

Chronic (Delayed) Under normal conditions of use, no health effects are expected.

Eye

Acute (Immediate) Causes mild eye irritation.

Chronic (Delayed) Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Ingestion

Acute (Immediate) Small amounts (less than a tablespoonful) swallowed are not likely to cause injury: swallowing amounts larger than that may cause gastrointestinal irritation.

Chronic (Delayed) Under normal conditions of use, no health effects are expected.

Other

Acute (Immediate) Under normal conditions of use, no health effects are expected.

Chronic (Delayed) Under normal conditions of use, no health effects are expected.

Other information

The systemic administration of quinolones, including ofloxacin, has led to lesions or erosions of the cartilage in weightbearing joints and other signs of arthropathy in immature animals of various species. Ofloxacin, administered systemically at 10 mg/kg/day in young dogs (equivalent to 110 times the maximum recommended daily adult ophthalmic dose) has been associated with these types of effects.

SECTION 12 : ECOLOGICAL INFORMATION

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| Ecotoxicity | : This material has not been tested for environmental effects. |
| Biodegradation | : No data available |
| Bioaccumulation | : No data available |
| Mobility in soil | : No data available |

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

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|-----------------|---|
| Product waste | Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator. |
| Packaging waste | Dispose of content and/or container in accordance with local, regional, national, and/or international regulations. |

SECTION 14 : TRANSPORT INFORMATION

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|-----------|---------------|
| DOT | Not regulated |
| TDG | Not regulated |
| IATA/ICAO | Not regulated |
| IMO/IMDG | Not regulated |

SECTION 15: REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications No data available

Ofloxacin (CAS: 82419-36-1)

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| Canada WHMIS Classifications of Substances | Not Listed |
| Canada DSL | Not available |
| Canada WHMIS | Not Listed |
| Ingredient Disclosure List | |
| EU EINECS | Not Listed |

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| EU CLP (1272/2008) Annex VI | Not Listed |
| Table 3.2 Classification | |
| EU CLP (1272/2008) Annex VI | Not Listed |
| Table 3.2 Labelling | |
| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Notes | Not Listed |
| Substances and Preparations | |
| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Safety Phrases | Not Listed |
| TSCA | Not Listed |
| U.S. OSHA | Not Listed |
| Process Safety Management | |
| Highly Hazardous Chemicals | |
| U.S. CAA (Clean Air Act) | Not Listed |
| 1990 Hazardous Air Pollutants | |
| U.S. CERCLA/SARA | Not Listed |
| Hazardous Substances and their R | |
| eportable Quantities | |
| U.S. CERCLA/SARA | Not Listed |
| Section 302 Extremely Hazardous | |
| Substances EPCRA RQs | |
| U.S. CERCLA/SARA | Not Listed |
| Section 302 Extremely Hazardous | |
| Substances TPQs | |
| U.S. CERCLA/SARA | Not Listed |
| Section 313 Emission Reporting | |
| U.S. California Proposition 65 | Not Listed |
| Carcinogens List | |
| U.S. California Proposition 65 | Not Listed |
| Developmental Toxicity | |
| U.S. California Proposition 65 | Not Listed |
| Reproductive Toxicity Female | |
| U.S. California Proposition 65 | Not Listed |
| Reproductive Toxicity Male | |

Benzalkonium Chloride (CAS: 63449-41-2)

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|-------------------------------|--------------------------|
| Canada WHMIS | Not Listed |
| Classifications of Substances | |
| Canada DSL | Present |
| Canada WHMIS | |
| Ingredient Disclosure List | Not Listed |
| EU EINECS | Present |
| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Classification | Xn; R21/22 C; R34 N; R50 |

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| EU CLP (1272/2008) Annex VI Table 3.2 Labelling | C N R:21/22-34-50 S:(2)-36/37/39-45-61 |
| EU CLP (1272/2008) Annex VI Table 3.2 Notes | Not Listed |
| Substances and Preparations | |
| EU CLP (1272/2008) Annex VI Table 3.2 Safety Phrases | S:(2)-36/37/39-45-61 |
| TSCA | Present |
| U.S. OSHA Process Safety Management | Not Listed |
| Highly Hazardous Chemicals | |
| U.S. CAA (Clean Air Act) 1990 Hazardous Air Pollutants | Not Listed |
| U.S. CERCLA/SARA Hazardous Substances and their R eportable Quantities | Not Listed |
| U.S. CERCLA/SARA Section 302 Extremely Hazardous Substances EPCRA RQs | Not Listed |
| U.S. CERCLA/SARA Section 302 Extremely Hazardous Substances TPQs | Not Listed |
| U.S. CERCLA/SARA Section 313 Emission Reporting | Not Listed |
| U.S. California Proposition 65 Carcinogens List | Not Listed |
| U.S. California Proposition 65 Developmental Toxicity | Not Listed |
| U.S. California Proposition 65 Reproductive Toxicity Female | Not Listed |
| U.S. California Proposition 65 Reproductive Toxicity Male | Not Listed |

Sodium Chloride (CAS: 7647-14-5)

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|---|---|
| Canada WHMIS Classifications of Substances | Uncontrolled product according to WHMIS classification criteria |
| Canada DSL | Present |
| Canada WHMIS Ingredient Disclosure List | Not Listed |
| EU EINECS | Present |
| EU CLP (1272/2008) Annex VI Table 3.2 Classification | Not Listed |
| EU CLP (1272/2008) Annex VI Table 3.2 Labelling | Not Listed |

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| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Notes | Not Listed |
| Substances and Preparations | |
| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Safety Phrases | Not Listed |
| TSCA | Present |
| U.S. OSHA | |
| Process Safety Management | Not Listed |
| Highly Hazardous Chemicals | |
| U.S. CAA (Clean Air Act) | |
| 1990 Hazardous Air Pollutants | Not Listed |
| U.S. CERCLA/SARA | |
| Hazardous Substances and their R | Not Listed |
| eportable Quantities | |
| U.S. CERCLA/SARA | |
| Section 302 Extremely Hazardous | Not Listed |
| Substances EPCRA RQs | |
| U.S. CERCLA/SARA | |
| Section 302 Extremely Hazardous | Not Listed |
| Substances TPQs | |
| U.S. CERCLA/SARA | |
| Section 313 Emission Reporting | Not Listed |
| U.S. California Proposition 65 | |
| Carcinogens List | Not Listed |
| U.S. California Proposition 65 | |
| Developmental Toxicity | Not Listed |
| U.S. California Proposition 65 | |
| Reproductive Toxicity Female | Not Listed |
| U.S. California Proposition 65 | |
| Reproductive Toxicity Male | Not Listed |

Hydrochloric acid (CAS: 7647-01-0)

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|-------------------------------|---|
| Canada WHMIS | A, D1A, E (listed under Hydrogen chloride); D1A, E; E (0.036% in |
| Classifications of Substances | aqueous solution, 0.36% in aqueous solution, 3.6% in aqueous soluti |
| | on); D1B, E (28% in aqueous solution); D1A, E (31.45% in |
| | aqueous solution, 35.2% in aqueous solution) |
| Canada DSL | Present |
| Canada WHMIS | |
| Ingredient Disclosure List | 1 % |
| EU EINECS | Present |
| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Classification | T; R23 C; R35 |
| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Labelling | T C R:23-35 S:(1/2)-9-26-36/37/39-45 |

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| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Notes | 5 |
| Substances and Preparations | |
| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Safety Phrases | S:(1/2)-9-26-36/37/39-45 |
| TSCA | Present |
| U.S. OSHA | |
| Process Safety Management | 5000 lb TQ; 5000 lb TQ |
| Highly Hazardous Chemicals | (anhydrous) |
| U.S. CAA (Clean Air Act) | |
| 1990 Hazardous Air Pollutants | Not Listed |
| U.S. CERCLA/SARA | |
| Hazardous Substances and their R | 5000 lb final RQ; 2270 kg final RQ |
| eportable Quantities | |
| U.S. CERCLA/SARA | |
| Section 302 Extremely Hazardous | 5000 lb EPCRA RQ (gas only) |
| Substances EPCRA RQs | |
| U.S. CERCLA/SARA | |
| Section 302 Extremely Hazardous | 500 lb TPQ (gas only) |
| Substances TPQs | |
| U.S. CERCLA/SARA | |
| Section 313 Emission Reporting | 1.0 % de minimis concentration (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size) |
| U.S. California Proposition 65 | |
| Carcinogens List | Not Listed |
| U.S. California Proposition 65 | |
| Developmental Toxicity | Not Listed |
| U.S. California Proposition 65 | |
| Reproductive Toxicity Female | Not Listed |
| U.S. California Proposition 65 | |
| Reproductive Toxicity Male | Not Listed |
| Water (CAS: 7732-18-5) | |
| Canada WHMIS | |
| Classifications of Substances | Uncontrolled product according to WHMIS classification criteria |
| Canada DSL | Present |
| Canada WHMIS | |
| Ingredient Disclosure List | Not Listed |
| EU EINECS | Present |
| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Classification | Not Listed |
| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Labelling | Not Listed |

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| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Notes | Not Listed |
| Substances and Preparations | |
| EU CLP (1272/2008) Annex VI | |
| Table 3.2 Safety Phrases | Not Listed |
| TSCA | Present |
| U.S. OSHA | |
| Process Safety Management | Not Listed |
| Highly Hazardous Chemicals | |
| U.S. CAA (Clean Air Act) | |
| 1990 Hazardous Air Pollutants | Not Listed |
| U.S. CERCLA/SARA | |
| Hazardous Substances and their R | Not Listed |
| eportable Quantities | |
| U.S. CERCLA/SARA | |
| Section 302 Extremely Hazardous | Not Listed |
| Substances EPCRA RQs | |
| U.S. CERCLA/SARA | |
| Section 302 Extremely Hazardous | Not Listed |
| Substances TPQs | |
| U.S. CERCLA/SARA | |
| Section 313 Emission Reporting | Not Listed |
| U.S. California Proposition 65 | |
| Carcinogens List | Not Listed |
| U.S. California Proposition 65 | |
| Developmental Toxicity | Not Listed |
| U.S. California Proposition 65 | |
| Reproductive Toxicity Female | Not Listed |
| U.S. California Proposition 65 | |
| Reproductive Toxicity Male | Not Listed |

SECTION 16: ADDITIONAL INFORMATION

SDS creation date : Jan 18, 2024
 SDS Revision date : NA
 Version # : 00

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---End of Safety Data Sheet---