

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name : Ofloxacin Ophthalmic Solution, USP 0.3%

Chemical Family : Fluoroquinolone

Synonyms : (\pm)-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

Details of the Supplier of the Safety Data Sheet : Caplin Steriles Limited, Survey No. 895 & 897, Guruvarakandigai, 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 ophthalmic solution is indicated for the treatment of infections caused by susceptible strains of bacteria.

Restrictions on use : Refer to the product insert and/or prescribing information for restrictions on use and contraindications

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 15-25°C (59-77°F), to maintain product integrity.
Use before date marked on carton and/or container.

Other Hazards : No data available

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent
Benzalkonium Chloride	63449-41-2	0.005%
Hydrochloric acid	7647-01-0	<1%
Ofloxacin	82419-36-1	0.3%
Sodium chloride	7647-14-5	<1%
Water for Injection	7732-18-5	Balance

Note:Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) and/or Sodium Hydroxide (CAS# 1310-73 -2, EINECS: 215-185-5) 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 Stevens-Johnson 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 treatment. Oxygen and airway management, including intubation should be administered as clinically indicated

Indication of any immediate medical attention and special treatment needed

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. : In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Refer to Section 8
Emergency Procedures	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.
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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 – 25° (59-77°F) to maintain product integrity. Use before expiration date marked on carton and/or container.

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	:	Clear, pale yellow to yellow
Odor Threshold	:	No data available
Appearance/Description	:	A clear, pale yellow to yellow color solution
Odor	:	No odor.
General Properties		
Boiling Point	:	No data available
Melting Point	:	Not relevant
pH	:	No data available
Viscosity	:	No data available
Specific Gravity/ Relative Density	:	= 1.005
Water solubility	:	Soluble
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
Burning Time	:	Not relevant
Environmental		
Octanol/Water Partition coefficient	:	No data available

SECTION 10 : Stability and Reactivity

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

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 weight-bearing 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

Toxicity	: This material has not been tested for environmental effects.
Persistence and degradability	: No data available
Bio accumulative potential	: No data available
Mobility in soil	: No data available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

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

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

SECTION 15: REGULATORY INFORMATION

DOT Designations:	Not classified as hazardous by DOT regulations.
EPA Designations:	Not Listed
FDA Designations:	Prescription only medication.
OSHA Designations:	Not Listed
SARA Title III:	Not listed under Section 313 of Toxic Release Reporting.
CALIFORNIA PROPOSITION 65:	Not Listed

SECTION 16: ADDITIONAL INFORMATION

SDS creation date	:	Apr 09, 2024
SDS Revision date	:	NA
Version #	:	00

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