SAFETY DATA SHEET

Section 1: Identification

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Product	**Ofloxacin Ophthalmic Solution USP 0.3%**
Distributor	SOLA Pharmaceuticals 655 Highlandia Drive, Ste B Baton Rouge, LA. 70810 Tel: 866.747.7365 Fax: 800.754.9550 www.solameds.us info@solameds.us
NDC Number	70512-793-05 (0.3% 5mL) 70512-793-10 (0.3% 10mL)

Section 2: Hazard(s) Identification

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Physical Hazards:	Not classifiable.
Health Hazards:	Not classifiable.
Symbol(s):	None.
Signal Word:	None.
Hazard Statement(s):	None.
Precautionary Statement(s):	None.
Hazards Not Otherwise Classified:	Not classifiable.

Supplementary Information:
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

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Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Ofloxacin	82419-36-1	7H-Pyrido [1,2,3-de]-1,4-benzoxazine-6-carboxylic acid, 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-, (+/-)-	$C_{18}H_{20}FN_3O_4$	361.37	0.3%

*The formula also contains Benzalkonium Chloride, 0.005% as preservative; Sodium Chloride and Water for injection. May also contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

Section 4: First-Aid Measures

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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:
Not determined. See package insert for more information.

Medical Conditions Aggravated by Exposure:
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 10mg/kg/day in young dogs (equivalent to 110 times the maximum recommended daily adult ophthalmic dose) has been associated with these types of effects. Quinolones, including ofloxacin, have been shown to cause arthropathy in immature animals after oral administration; however, topical ocular administration of ofloxacin to immature animals has not shown any arthropathy. There is no evidence that the ophthalmic dosage form of ofloxacin has any effect on weight bearing joints.

Notes to Physician:
Treat supportively and symptomatically.

Section 5: Fire-Fighting Measures

Section 5, Fire-Fighting Measures

Flammability:
Not determined.

Suitable Extinguishing Media:
Use extinguishing media suitable for surrounding materials such as dry chemical, carbon dioxide, halon, water spray or fog, and foam.

Unsuitable Extinguishing Media:
Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:
Products of combustion may be toxic.

Other Specific Hazards:
Not determined.
Special Protective Equipment/Precautions for Firefighters:
Wear self-contained breathing apparatus and full and protective gear.

Section 6: Accidental Release Measures

Section 6, Accidental Release Measures

Personal Precautions:
Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Personal Protective Equipment:
For personal protection see section 8.
Methods for Cleaning Up:
Spills may be absorbed with a wet disposable towel or other suitable adsorbent. Carefully collect and place in a suitable, properly labeled container for disposal. Clean area using soap and water.
Environmental Precautions:
Product as administered to patients presents a negligible impact on the environment.
Reference to Other Sections:
Refer to Sections 8, 12 and 13 for further information.

Section 7: Handling and Storage

Section 7, Handling and Storage

Precautions for Safe Handling:
Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment. Wash thoroughly after handling. Contaminated clothing should be laundered before reuse. 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 the product in original container with the cap tightly closed at a controlled room temperature 15°C – 25°C (59°F – 77°F). KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. Store according to label and/or product insert information. Store away from oxidizing agents and acids.
Specific End Use:
Pharmaceuticals.

Section 8: Exposure Controls / Personal Protection

Section 8, Exposure Controls / Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Ofloxacin	Not established

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:
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.

Hand Protection:
Not 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.
Skin Protection:
Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

Section 9: Physical and Chemical Properties

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Physical State/Color:	Clear, pale yellow to yellow solution.
Odor:	No data available.
Odor Threshold:	No data available.
pH:	6.2 – 6.8.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Completely miscible.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	Aqueous.
Volatile Component:	Less than 1%.

Section 10: Stability and Reactivity

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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):
Extreme heat or cold.
Incompatible Materials:
Similar to water; e.g. strong acids, base, alkali metals, alkali hydrides and silver preparations.
Hazardous Decomposition Products:
Products of combustion may be toxic.
Hazardous Polymerization:
Will not occur.

Section 11: Toxicological Information

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Information on the Likely Routes of Exposure:

Toxicity:

Ofloxacin may be irritating to the eye/nose/throat and cause asthenia, malaise, seizures, anxiety, cognitive change, vertigo, cough, bronchospasm, tachycardia, syncope, hepatic dysfunction, kidney dysfunction, and hypersensitivity reactions.

Inhalation:

May irritate the respiratory system.

Ingestion:

No data available.

Skin Contact:

Ofloxacin should be discontinued at the first appearance of a skin rash or any other sign of hypersensitivity reaction.

Eye Contact:

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	Type	Dose
Ofloxacin	Male Rats	Oral	LD_{50}	3,590 mg/kg
Ofloxacin	Female Rats	Oral	LD_{50}	3,750 mg/kg
Ofloxacin	Male Mice	Oral	LD_{50}	5,450 mg/kg
Ofloxacin	Female Mice	Oral	LD_{50}	5,290 mg/kg
Ofloxacin	Male	Oral	LD_{Lo}	17 mg/kg/d
Ofloxacin	Female	Oral	LD_{Lo}	24 mg/kg/d
Ofloxacin	Male Rats	Intravenous	LD_{50}	273 mg/kg
Ofloxacin	Female Rats	Intravenous	LD_{50}	276 mg/kg
Ofloxacin	Male Mice	Intravenous	LD_{50}	280 mg/kg
Ofloxacin	Female Mice	Intravenous	LD_{50}	233 mg/kg
Ofloxacin	Male Rats	Subcutaneous	LD_{50}	7,070 mg/kg
Ofloxacin	Female Rats	Subcutaneous	LD_{50}	9,000 mg/kg
Ofloxacin	Male Mice	Subcutaneous	LD_{50}	10,000 mg/kg
Ofloxacin	Female Mice	Subcutaneous	LD_{50}	10,000 mg/kg

Reproductive Toxicity – Embryotoxicity:

Compound	Species	Dose	Effect(s)
Ofloxacin	Rats	160 mg/kg/d	Embryotoxicity/ Not Teratogenic
Ofloxacin	Rabbits	810 mg/kg/d	Embryotoxicity/ Not Teratogenic

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: None.
Reproductive Effects: No data available.
Carcinogenicity: Long-term studies to determine the carcinogenic potential of Ofloxacin have not been conducted.

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:
Ofloxacin was not mutagenic in the Ames test, in vitro and in vivo cytogenic assay, sister chromatid exchange assay (Chinese hamster and human cell lines), unscheduled DNA synthesis (UDS) assay using human fibroblasts, the dominant lethal assay, or mouse micronucleus assay. Ofloxacin was positive in the UDS test using rat hepatocyte, and in the mouse lymphoma assay.
Fertility:
In fertility studies in rats, Ofloxacin did not affect male or female fertility or morphological or reproductive performance at oral dosing up to 360 mg/kg/day (equivalent to 4000 times the maximum recommended daily ophthalmic dose).
Pregnancy:
Pregnancy category C Ofloxacin has been shown to have an embryocidal effect in rats and in rabbits when given in doses of 810 mg/kg/day (equivalent to 9000 times the maximum recommended daily ophthalmic dose) and 160 mg/kg/day (equivalent to 1800 times the maximum recommended daily ophthalmic dose). These dosages resulted in decreased fetal body weight and increased fetal mortality in rats and rabbits, respectively. Minor fetal skeletal variations were reported in rats receiving doses of 810 mg/kg/day. Ofloxacin has not been shown to be teratogenic at doses as high as 810 mg/kg/day and 160 mg/kg/day when administered to pregnant rats and rabbits, respectively.
Nursing Mothers:
In nursing women a single 200mg oral dose resulted in concentrations of Ofloxacin in milk which were similar to those found in plasma. It is not known whether Ofloxacin is excreted in human milk following topical ophthalmic

administration. Because of the potential for serious adverse reactions from Ofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Drug Interactions:

Specific drug interaction studies have not been conducted with Ofloxacin ophthalmic solution. However, the systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine, and enhance the effects of the oral anticoagulant warfarin and its derivatives, and, has been associated with transient elevations in serum creatinine in patients receiving cyclosporine concomitantly.

Aspiration Hazard:

No data available.

Section 12: Ecological Information

Section 12, Ecological Information

Ecotoxicity

Aquatic:	No data available.
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.

Section 13: Disposal Considerations

Section 13, Disposal Considerations

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

Section 14: Transport Information

Section 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.

Section 15: Regulatory Information

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US Federal Regulations:

Toxic Substance Control Act (TSCA):	Not listed.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.
State Regulations	
California Proposition 65:	Not listed.

Not made with natural rubber latex.

Section 16: Other Information

Section 16, Other Information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

SOLA shall not be held liable for any damage resulting from handling or from contact with the above product. SOLA reserves the right to revise this Safety Data Sheet.