

SAFETY DATA SHEET

Ofloxacin Otic Solution, 0.3%

1. IDENTIFICATION

Product Identifier:	Ofloxacin Otic Solution, 0.3%
Synonyms:	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-, (+/-)-
National Drug Code (NDC):	50383-025-05 50383-025-10
Recommended Use:	Pharmaceutical. 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.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards:	Not classifiable.	
Health Hazards:	Eye irritation	Category 2B
Symbol(s):	None.	
Signal Word:	Warning.	
Hazard Statement(s):	H320 Causes mild eye irritation.	
Precautionary Statement(s):	P264 Wash hands thoroughly after handling.	
	P280 Wear protective gloves/protective clothing/eye protection/face protection.	
	P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.	
	+ P351	
	+ P338	
	P337 IF eye irritation persists: Get medical advice/attention.	
	+ P313	

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P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Ofloxacin	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-, (+/-)-	82419-36-1	C ₁₈ H ₂₀ FN ₃ O ₄	361.38	0.3%

The formula also contains Benzalkonium Chloride 0.0025%, Purified Water and Sodium Chloride. Hydrochloric Acid and Sodium Hydroxide added to adjust pH.

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

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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:

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.

Medical Conditions Aggravated by Exposure:

Not determined.

Notes to Physician:

Treat supportively and symptomatically.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media:

Use water, carbon dioxide, dry chemical or water spray.

Unsuitable Extinguishing Media:

Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products:

No data available.

Other Specific Hazards:

Closed containers may explode from the heat of fire.

Special Protective Equipment and Precautions for Firefighters:

Wear self-contained breathing apparatus and full and protective gear.

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.

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Methods for Cleaning Up: 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 between 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light. Store away from oxidizing agents and acids.

Specific End Use: Pharmaceutical drug product.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Ofloxacin	Not established	Not established

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

Respiratory Protection: Not required for the normal use of this product. 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: Avoid contact with eyes. 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 are recommended for handling solutions and 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

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powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

General Hygiene Considerations:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Clear, greenish yellow aqueous solution.
Odor:	No odor.
Odor Threshold:	No data available.
pH:	No data available.
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):	No data available.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
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. Do not freeze.
Incompatible Materials:	None.
Hazardous Decomposition Products:	None expected.

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11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation: May cause irritation to the respiratory system.

Ingestion: May cause gastrointestinal irritation if swallowed in large quantities.

Skin Contact: Not expected to cause skin irritation.

Eye Contact: Causes mild 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

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Ofloxacin	Rat	Oral	LD ₅₀	3,590 mg/kg
Ofloxacin	Mouse	Oral	LD ₅₀	3,266 mg/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
Ofloxacin	Reproductivity/ Development	Rabbit	No route specified	160 mg/kg/day	Not specified	Embryotoxic but not teratogenic
Ofloxacin	Fertility	Rat	No route specified	360 mg/kg	Not specified	No adverse effects on fertility
Ofloxacin	Reproductivity/ Development	Rat	No route specified	810 mg/kg/day	Not specified	Embryotoxic but not teratogenic

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Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
Ofloxacin	Ames test	Salmonella typhimurium	Mixed results
Ofloxacin	Dominant lethal assay	Not specified	Negative
Ofloxacin	In vivo and in vitro cytogenic assay	Not specified	Negative
Ofloxacin	Lymphoma assay	Mouse	Positive
Ofloxacin	Micronucleus assay	Mouse	Negative
Ofloxacin	Sister chromatid exchange assay	Chinese hamster and human cells	Negative
Ofloxacin	Unscheduled DNA repair test	Human fibroblasts	Negative
Ofloxacin	Unscheduled DNA repair test	Rat hepatocytes	Positive

Aspiration Hazard: No data available.
Toxicokinetics/Metabolism: No data available.
Target Organ Effects: No data available.
Systemic Effects: No data available.

Reproductive Effects: Pregnancy Category C. Ofloxacin has been shown to have an embryocidal effect in rats at a dose of 810 mg/kg/day and in rabbits at 160 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.

Carcinogenicity: Long-term studies to determine 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.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available.

Terrestrial Toxicity: 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.

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13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

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

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

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

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Ofloxacin	No

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Ofloxacin	Listed	Listed	Not Listed

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California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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