



**Ofloxacin Otic Solution 0.3% (Sterile)  
MATERIAL SAFETY DATA SHEET**

Effective Date: 3/7/08

Supersedes: None

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**Section 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

**Product Name:** Ofloxacin Otic Solution 0.3% (Sterile)

**For Information:** 1-800-553-5340

**Product Code(s):**

**For Emergency:** 1-800-535-5053

**NDC No(s):** NDC 24208-410-05 (5 ml)  
NDC 24208-410-10 (10 ml)

**Chemical Family:** Anti-Infective (Anti-Bacterial)

**Manufacturer:** Bausch & Lomb Incorporated

**Address:** 1400 N. Goodman Street  
Rochester, New York 14609

**Section 2: COMPOSITION / INFORMATION ON INGREDIENTS**

CAS #	COMPONENT NAME	% W/W	OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES										UNITS	
			OSHA PEL TWA /STEL	ACGIH TLV TWA /STEL	NIOSH REL TWA /STEL	IRELAND TWA /STEL	HSE TWA /STEL							
82419-36-1	Ofloxacin	0.3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
8001-54-5	Benzalkonium Chloride	0.0025	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7647-14-5	Sodium Chloride	0.9	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7732-18-5	Purified Water, USP	> 98	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
TOTAL		100												

May also contain Hydrochloric Acid and/or Sodium Hydroxide to adjust pH.

N/E: Not Established OSHA: Occupational Safety & Health Administration

N/A: Not Applicable PPM: Parts per Million

ACGIH: American Conference of Governmental Industrial Hygienists

NIOSH: National Institute for Occupational Safety & Health

TWA: 8-Hour Time-Weighted Average

STEL: Short-Term Exposure Limit

C: Ceiling Limit

REL: Recommended Exposure Limit

**Section 3: HAZARDS IDENTIFICATION**

**EMERGENCY OVERVIEW**

***Ofloxacin Otic Solution 0.3% is a sterile, anti-infective (anti-bacterial) product for otic (ear) use only. NOT FOR OPHTHALMIC USE. NOT FOR INJECTION. Do Not Use if there exists any hypersensitivity to ofloxacin, to other quinolones, or to any ingredient in this product. WARNING: Keep out of reach of children.***

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#### Section 3: HAZARDS IDENTIFICATION (cont.)

##### **PRECAUTIONS:**

Ofloxacin Otic Solution 0.3% is a sterile, aqueous anti-infective (anti-bacterial) product for otic use only. It is indicated for the treatment of ear infections caused by certain bacteria (see product literature).

**Do Not Use:** if there exists hypersensitivity to ofloxacin, to other quinolones, or to any ingredient in this product.

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. If allergic reaction to ofloxacin is suspected, stop the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management, including intubation, should be administered as clinically indicated.

Use only in accordance with product literature and prescribing information.

**WARNING: Keep out of reach of children.**

##### **POTENTIAL HEALTH EFFECTS**

###### **EYE:**

Not expected to be irritating to the eyes.

###### **SKIN:**

Not expected to be irritating to skin or mucous membranes when used as directed.

###### **INGESTION:**

May be harmful if swallowed.

###### **INHALATION:**

Unlikely to be hazardous when used as directed. However, if actively concentrated and inhaled, it may cause respiratory tract irritation.

##### **CHRONIC HEALTH EFFECTS**

As with other anti-infective preparations, prolonged use may result in over-growth of nonsusceptible organisms, including fungi. The systemic administration of quinolones, including ofloxacin at doses much higher than given or absorbed by the otic route, has led to lesions or erosions of the cartilage in weight-bearing joints and other signs of arthropathy in immature animals of various species.

Refer to the product insert for additional information.

##### **CARCINOGENICITY:**

**NTP:** No ingredients listed.

**IARC:** No ingredients listed.

**OSHA:** No ingredients listed.

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#### Section 4: FIRST AID MEASURES

##### **EYES:**

For accidental applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention.

##### **SKIN:**

Wash contaminated area with soap and water. Get medical attention if irritation develops.

##### **INGESTION:**

Do Not Induce Vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If Ofloxacin Otic Solution 0.3% (Sterile) is accidentally ingested, contact a physician immediately and provide product-prescribing information.

##### **INHALATION:**

No inhalation exposure expected with this formulation under normal conditions of use. If inhaled, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Contact a physician immediately.

##### **ADDITIONAL NOTES TO PHYSICIAN:**

For additional guidance, refer to the product insert. Contact the local Poison Control Center.

#### Section 5: FIRE FIGHTING MEASURES

##### **FLAMMABLE PROPERTIES:**

**Flash Point:** Not Applicable

**Method:** NA

##### **EXTINGUISHING MEDIA:**

Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

##### **HAZARDOUS COMBUSTION PRODUCTS:**

Carbon dioxides, nitrogen oxides, sulfur oxides, halogenated compounds, hydrogen chloride and other hazardous products of combustion.

##### **SPECIAL FIRE FIGHTING INSTRUCTIONS:**

As in any fire, wear self-contained breathing apparatus and full protective gear.

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### Section 6: ACCIDENTAL RELEASE MEASURES

#### General Information:

Use appropriate protective equipment and engineering controls (refer to Section 8).

#### Specific Information:

Ventilate area. 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. Minimize contact of spilled material with soils to prevent runoff to surface waterways.

Dispose of in accordance with Section 13.

### Section 7: HANDLING AND STORAGE

#### HANDLING:

Use only in accordance with product literature. Wash hands thoroughly with warm water and soap after handling.

#### STORAGE:

Store product in original container, with cap tightly closed, at room temperature: 25°C (77°F), excursions permitted to 15°-30°C (59°-86°F). Protect from light.

Shelf Life: Expiration date is listed on each package.

### Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

#### ENGINEERING CONTROLS:

Not required during normal clinical use

#### RESPIRATORY PROTECTION:

Not required during normal clinical use.

#### SKIN PROTECTION:

Not required during normal clinical use. Wash thoroughly with warm water and soap after handling. Impervious chemical resistant gloves and appropriate protective clothing are recommended when directly handling bulk product.

#### EYE PROTECTION:

Not required during normal clinical use. Appropriate eye protection is required when handling bulk product.

#### ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:

No special recommendations during normal clinical use.

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### Section 9: PHYSICAL AND CHEMICAL PROPERTIES

#### PHYSICAL PROPERTIES:

**Appearance / Physical State:** Clear, greenish-yellow solution  
**Odor/Threshold Limit:** Odorless

#### CHEMICAL PROPERTIES:

<b>Boiling Point:</b>	Not Available	<b>Melting Point:</b>	Not Applicable
<b>Vapor Pressure:</b>	Not Available	<b>Density:</b>	0.95-1.05 g/mL
<b>Solubility In Water:</b>	Soluble	<b>Specific Gravity (H<sub>2</sub>O = 1):</b>	Not Determined
<b>Ph:</b>	6.0-7.0	<b>Evaporation Rate:</b>	Not Available
<b>Freezing Point:</b>	Not Available	<b>Molecular Weight:</b>	Not Available

### Section 10: STABILITY AND REACTIVITY

#### GENERAL:

Stable

#### CONDITIONS TO AVOID:

Extreme heat or cold. Protect from light.

#### INCOMPATIBLE MATERIALS:

None identified.

#### HAZARDOUS POLYMERIZATION:

Will not occur.

#### HAZARDOUS DECOMPOSITION PRODUCTS:

Carbon dioxides, nitrogen oxides, sulfur oxides, halogenated compounds, and hydrogen chloride.

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### Section 11: TOXICOLOGICAL INFORMATION

#### ***Carcinogenesis, Mutagenesis, Impairment of Fertility:***

Long-term studies to determine the carcinogenic potential of ofloxacin have not been conducted. Ofloxacin was not mutagenic in the Ames test, the sister chromatid exchange assay (Chinese hamster and human cell lines), the unscheduled DNA synthesis (UDS) assay using human fibroblasts, the dominant lethal assay, or the mouse micronucleus assay. Ofloxacin was positive in the rat hepatocyte UDS assay, and in the mouse lymphoma assay. In rats, ofloxacin did not affect male or female reproductive performance at oral doses up to 360 mg/kg/day. This would be over 1000 times the maximum recommended clinical dose, based upon body surface area, assuming total absorption of ofloxacin from the ear of a patient treated with ofloxacin otic solution 0.3% twice per day.

#### ***Teratogenic Effects:***

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. These dosages resulted in decreased fetal body weights and increased fetal mortality in rats and rabbits respectively. Minor fetal skeletal variations were reported in rats receiving doses at 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.

Ofloxacin has not been shown to have any adverse effects on the developing embryo or fetus at doses relevant to the amount of ofloxacin that will be delivered ototopically at the recommended clinical doses.

**RTECS No.:**            **UU8815500**

#### **Ofloxacin**

**Toxicity Data:**        ORL-RAT                            LD50:3590 MG/KG

**RTECS No.:**            **BO3150000**

#### **Benzalkonium Chloride**

**Toxicity Data:**        ORL-RAT                            LD50: 240 MG/KG

**RTECS No.:**            **VZ4725000**

#### **Sodium Chloride**

**Toxicity Data:**        ORL-RAT                            LD50: 3 GM/KG  
                              ORL-MOUSE                        LD50: 4 GM/KG

**NOTE:** Only selected Registry of Toxic Effects of Chemical Substances (RTECS) data is presented here. See actual entry in RTECS for complete information.

Refer to Section 3 for additional acute / chronic hazard information.

### Section 12: ECOLOGICAL INFORMATION

No data available on the environmental impact of this product.

### Section 13: DISPOSAL CONSIDERATIONS

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All disposal methods must be in compliance with all Federal, State/Provincial and local laws and regulations. Regulations may vary in different locations. Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

### Section 14: TRANSPORT INFORMATION

	US DOT	IATA	IMO	RID/ADR	Canadian DG
<b>Shipping Name:</b>	Not Regulated	Not Regulated	No Information Available	No Information Available	No Information Available
<b>Hazard Class:</b>	NA	NA			
<b>UN Number:</b>	NA	NA			
<b>Package Group:</b>	NA	NA			

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce. Hazard class definitions (49 CFR, Part 173) are not applicable to this product.

### Section 15: REGULATORY INFORMATION

#### OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):

Although technically exempt from the Occupational Safety & Health Administration (OSHA) Hazard Communication Standard, this product would be considered hazardous.

#### TOXIC SUBSTANCE CONTROL ACT (TSCA):

CAS# 82419-36-1 is listed on the TSCA inventory.  
CAS# 8001-54-5 is listed on the TSCA inventory.  
CAS# 7647-14-5 is listed on the TSCA inventory.  
CAS# 7732-18-5 is listed on the TSCA inventory.

#### SARA TITLE III (Superfund Amendments and Reauthorization Act):

SECTION 302 (Extremely Hazardous Substances): No Components Listed  
SECTION 311, 312 (Hazard Categories): Acute, Chronic  
SECTION 313 (Toxic Chemicals): No Components Listed

#### CALIFORNIA PROPOSITION 65:

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels that would require a warning under the statute.

### Section 16: OTHER INFORMATION

*To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb Incorporated nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb Incorporated or any of its subsidiaries be liable for any special, incidental or consequential damages.*