

Safety Data Sheet



Section 1: Identification

Product identifier

- Product Name** • **Ofloxacin Otic Solution, 0.3%**
Product Code • AB41007; AB41009; Core No. 410

Relevant identified uses of the substance or mixture and uses advised against

- Recommended use** • Finished Pharmaceutical Product; 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** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

- Manufacturer** • Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com
- Telephone (General)** • 1-800-553-5340

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

- UN GHS** • Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

- 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 15-30°C (59-86°F), to maintain product integrity. Use before expiration date marked on carton and/or container. Protect from light.

Other hazards

UN GHS

- No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Benzalkonium Chloride	CAS:63449-41-2 EINECS:264-151-6	0.0025%	UN GHS: Skin Corr. 1B; Acute Tox. Oral 4; Acute Tox. Dermal 4; Aquatic Acute 1
Hydrochloric acid	CAS:7647-01-0 EINECS:231-595-7	< 1%	UN GHS: Skin Corr. 1A; Acute Tox. Inhal. 3; Press. Gas - Comp
Ofloxacin	CAS:82419-36-1	0.3%	UN GHS: NDA
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	0.9%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Classification criteria not met

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.

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of 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

Personal 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.

Section 7 - Handling and Storage

Precautions for 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°C (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					
	Result	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; 7 mg/m ³ Ceiling	5 ppm Ceiling; 7 mg/m ³ Ceiling

Exposure Control Notations

ACGIH

•Hydrochloric acid (7647-01-0): **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.

Hands

- Gloves are not required under normal handling conditions.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Clear, greenish yellow aqueous solution.
Color	Greenish yellow.	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	6 to 7
Specific Gravity/Relative Density	= 1.005	Density	0.95 to 1.05 g/mL
Water Solubility	No data available	Viscosity	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**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**Information on toxicological effects****Other Material Information**

- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

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
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	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)**Chronic (Delayed)**

- Not expected to cause skin irritation.
- Under normal conditions of use, no health effects are expected.

Eye**Acute (Immediate)****Chronic (Delayed)**

- Causes mild eye irritation.
- 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)****Chronic (Delayed)**

- Small amounts (less than a tablespoonful) swallowed are not likely to cause injury: swallowing amounts larger than that may cause gastrointestinal irritation.
- Under normal conditions of use, no health effects are expected.

Other**Acute (Immediate)****Chronic (Delayed)**

- Under normal conditions of use, no health effects are expected.
- 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

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

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

	UN number	UN proper shipping name	Transport hazard class(es)	Packing group	Environmental hazards
DOT	NDA	not regulated	NDA	NDA	NDA

TDG	NDA	not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	not regulated	NDA	NDA	NDA

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

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

SARA Hazard Classifications • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Ofloxacin	82419-36-1	No	No	No
Benzalkonium Chloride	63449-41-2	Yes	Yes	Yes
Hydrochloric acid	7647-01-0	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Hydrochloric acid	7647-01-0	A, D1A, E (listed under Hydrogen chloride); D1A, E; E (0.036% in aqueous solution, 0.36% in aqueous solution, 3.6% in aqueous solution); D1B, E (28% in aqueous solution); D1A, E (31.45% in aqueous solution, 35.2% in aqueous solution)
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

Canada - WHMIS - Ingredient Disclosure List

• Hydrochloric acid	7647-01-0	1 %
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

Europe

Other**EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification**

• Hydrochloric acid	7647-01-0	T; R23 C; R35
• Benzalkonium Chloride	63449-41-2	Xn; R21/22 C; R34 N; R50
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Hydrochloric acid	7647-01-0	T C R:23-35 S:(1/2)-9-26-36/37/39-45
• Benzalkonium Chloride	63449-41-2	C N R:21/22-34-50 S:(2)-36/37/39-45-61
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Notes - Substances and Preparations

• Hydrochloric acid	7647-01-0	5
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Hydrochloric acid	7647-01-0	S:(1/2)-9-26-36/37/39-45
• Benzalkonium Chloride	63449-41-2	S:(2)-36/37/39-45-61
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

United States**Labor****U.S. - OSHA - Process Safety Management - Highly Hazardous Chemicals**

• Hydrochloric acid	7647-01-0	5000 lb TQ; 5000 lb TQ (anhydrous)
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

Environment**U.S. - CAA (Clean Air Act) - 1990 Hazardous Air Pollutants**

• Hydrochloric acid	7647-01-0	
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Hydrochloric acid	7647-01-0	5000 lb final RQ; 2270 kg final RQ
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed

• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs

• Hydrochloric acid	7647-01-0	5000 lb EPCRA RQ (gas only)
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

U.S. - CERCLA/SARA - Section 302 Extremely Hazardous Substances TPQs

• Hydrochloric acid	7647-01-0	500 lb TPQ (gas only)
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

U.S. - CERCLA/SARA - Section 313 - Emission Reporting

• Hydrochloric acid	7647-01-0	1.0 % de minimis concentration (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Hydrochloric acid	7647-01-0	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Hydrochloric acid	7647-01-0	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Hydrochloric acid	7647-01-0	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Hydrochloric acid	7647-01-0	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed

• Sodium chloride	7647-14-5	Not Listed
• Ofloxacin	82419-36-1	Not Listed
• Water	7732-18-5	Not Listed

Section 16 - Other Information

Last Revision Date	<ul style="list-style-type: none">• 14/May/2015
Preparation Date	<ul style="list-style-type: none">• 14/May/2015
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