



Besivance™ (besifloxacin ophthalmic suspension) 0.6%

MATERIAL SAFETY DATA SHEET

Effective Date: 4/2/09 Supersedes: None

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Section 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT:

Product Name: Besivance™ (besifloxacin ophthalmic suspension) 0.6%
Product Code(s): Core 445
NDC No(s): 24208-446-05 (5 mL in 7.5 mL bottle)
Intended Use: For topical ophthalmic use only
Chemical Name: 7-[(3*R*)-3-Aminohexahydro-1*H*-azepin-1-yl]-8-chloro-1-cyclopropyl-6 fluoro-1,4-dihydro-4-oxo-3-quinolinecarboxylic acid monohydrochloride
Chemical Family: Fluoroquinolone
Formula: C₁₉H₂₁ClFN₃O₃ · HCl

COMPANY IDENTIFICATION:

Bausch & Lomb, Incorporated
1400 N. Goodman Street
Rochester, New York 14609

For Information: 1-800-553-5340

EMERGENCY TELEPHONE NUMBER:

24-Hour Emergency: 1-800-535-5053

Section 2: HAZARDS IDENTIFICATION

CLASSIFICATION: Acute toxicity; Category 5

LABELING:

Pictograms: (None required)

Signal Word: Warning

Hazard Statements: May be harmful if swallowed
Avoid inhalation of mists.
May cause eye irritation in sensitive individuals.

Precautionary Statements: **Not for injection into the eye.**
Use only in accordance with label instructions and supplied prescribing information.
Avoid release to the environment.
Keep out of reach of children.

PRECAUTIONS:

This product is intended for use as an antibacterial ophthalmic suspension. The toxicological properties of this material have not been fully characterized. If you are sensitive to any of its components, do not use. Refer to the full prescribing

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Section 2: HAZARDS IDENTIFICATION (cont.)

information for a comprehensive review of all warnings and precautions. Use only in accordance with label instructions and supplied prescribing information.

KEEP OUT OF REACH OF CHILDREN.

POTENTIAL HEALTH EFFECTS

EYE:

May cause irritation in sensitive individuals.

SKIN:

Prolonged exposure may cause irritation to skin or mucous membranes.

INGESTION:

May be harmful if swallowed.

INHALATION:

Avoid breathing vapors or mists.

CHRONIC HEALTH EFFECTS

Unknown

CARCINOGENICITY:

NTP: No ingredients listed.

IARC: No ingredients listed.

OSHA: No ingredients listed.

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

CAS #	Chemical Identity	Concentration, % W/W	EINECS / ELINCS #
405165-61-9	Besifloxacin Hydrochloride	0.6	NA
7647-14-5	Sodium Chloride	Proprietary	231-598-3
6381-92-6	Edetate Disodium Dihydrate	Proprietary	NA
9003-01-4	Polycarbophil	Proprietary	NA
69-65-8	D-Mannitol	Proprietary	200-711-8
9003-11-6	Poloxamer 407	Proprietary	NA
1310-73-2	Sodium Hydroxide	Proprietary	215-185-5
8001-54-5	Benzalkonium Chloride	0.01	NA
7732-18-5	Water for Injection	Proprietary	231-791-2

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Section 4: FIRST AID MEASURES

EYES:

Immediately flush eyes with plenty of water. If discomfort or irritation develops, seek medical attention.

SKIN:

Wash with soap and water. If discomfort or irritation develops, seek medical attention.

INGESTION:

If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain medical attention immediately.

INHALATION:

No specific treatment is necessary since this material is not likely to be hazardous by inhalation under conditions of intended use. However, if exposed to excessive levels of mists remove to fresh air and get medical attention if cough or other symptoms develop.

Section 5: FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

Flash Point: Non-Combustible

Method: NA

EXTINGUISHING MEDIA:

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

HAZARDOUS COMBUSTION PRODUCTS:

None identified.

SPECIAL FIRE FIGHTING INSTRUCTIONS:

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

Section 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:

Wear suitable protective eyewear, clothing, respiratory protection, rubber boots and rubber gloves. Shut off all sources of ignition. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

ENVIRONMENTAL PRECAUTIONS:

Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

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Section 6: ACCIDENTAL RELEASE MEASURES (cont.)

METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

Isolate hazard area. Prevent from entering drains and sewers. Cover with vermiculite or other suitable inert material, pick up and place in closed containers. Transport outdoors and hold for waste disposal. Ventilate area and wash spill site after material pickup is complete.

Refer to Section 13 for appropriate disposal procedures.

Section 7: HANDLING AND STORAGE

HANDLING:

Use only in accordance with label instructions and supplied product literature.

STORAGE:

Store at 15°- 25°C (59° - 77°F). Protect from Light.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

CONTROL PARAMETERS:

CAS #	COMPONENT NAME	OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES												
		OSHA PEL TWA /STEL		ACGIH TLV TWA /STEL		NIOSH REL TWA /STEL		IRELAND TWA /STEL		HSE TWA /STEL		B&L IOEL ² TWA /STEL		UNITS
405165-61-9	Besifloxacin Hydrochloride ¹	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	0.04	NE	mg/m ³
7647-14-5	Sodium Chloride	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
6381-92-6	Edetate Disodium Dihydrate	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
9003-01-4	Polycarbophil ³	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
69-65-8	D-Mannitol	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
9003-11-6	Poloxamer 407	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
1310-73-2	Sodium Hydroxide	2	NE	NE	2	NE	2	NE	2	NE	2	NE	NE	mg/m ³
8001-54-5	Benzalkonium Chloride	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA
7732-18-5	Water for Injection	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NA

NOTE: Limits/standards shown for guidance only. Follow applicable regulations.

N/E: Not Established

OSHA: Occupational Safety & Health Administration

TWA: 8-Hour Time-Weighted Average

STEL: Short-Term Exposure Limit

ACGIH: American Conference of Governmental Industrial Hygienists

IOEL: Internal Occupational Exposure Limit

N/A: Not Applicable

PPM: Parts Per Million

C: Ceiling Limit

REL: Recommended Exposure Limit

NIOSH: National Institute for Occupational Safety & Health

¹ NOTE: The biological activity of this material has not been fully characterized. Exposure to this material must be minimized.

² For In-House Use Only

³ Manufacturer's recommended 8-hour TWA exposure limit is 0.05 mg/m³

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Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION (cont.)

ENGINEERING CONTROLS:

Use with good general ventilation.

RESPIRATORY PROTECTION:

No special controls or personal protection required under conditions of intended use.

In the event of a spill, a NIOSH-certified air-purifying respirator equipped with the appropriate cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

EYE PROTECTION:

No special controls or personal protection required under conditions of intended use.

In the event of a spill, appropriate eye protection should be worn.

SKIN PROTECTION:

No special controls or personal protection required under conditions of intended use.

In the event of a spill, use rubber gloves.

ADDITIONAL PROTECTIVE CLOTHING & EQUIPMENT:

None identified

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid
Color:	Off-white, opaque
Odor:	No Odor
Odor Threshold:	Not determined
pH-Value:	6.0 – 7.0 (through shelf life)
Melting Point:	Not applicable
Freezing Point:	Not determined
Initial Boiling Point:	Not determined
Flash Point:	Not applicable
Evaporation Rate:	Not determined
Flammability:	Not applicable
Explosion Limits:	Not determined
Vapor Pressure:	Not determined
Vapor Density:	Not determined
Specific Gravity (H₂O=1):	1.03
Solubility:	Not soluble in water
Partition Coefficient:	Not applicable
Auto-Ignition Temperature:	Not determined
Decomposition Temperature:	Not determined
Osmolality:	290 mOsm/kg
Viscosity:	~1500 cps

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Section 10: STABILITY AND REACTIVITY

GENERAL:

Stable under normal conditions.

INCOMPATIBLE MATERIALS AND CONDITIONS TO AVOID:

None identified.

HAZARDOUS POLYMERIZATION:

Will not occur.

HAZARDOUS DECOMPOSITION:

None identified.

Section 11: TOXICOLOGICAL INFORMATION

Besifloxacin Hydrochloride

Acute Oral Toxicity:	Category 5: LD 50:>2,000 mg/kg species: Rat (male)
Short-Term Toxicity Study:	NOEL: 200 mg/kg/day (7-Day oral gavage toxicity in rats) NOEL: <100 mg/kg/day (14-day oral gavage toxicity in dogs)
Repeated Oral Dose:	NOEL: 500 mg/kg/day (28-day oral gavage toxicity in rats) NOEL: 5 mg/kg/day (28-day oral gavage toxicity in dogs)
Chronic Toxicity:	No data available
Skin Sensitization:	No data available
Carcinogenic Effects:	No data available.
Mutagenic effects:	Ames test: Negative Chromosomal aberration test: Positive Micronucleus test: Positive (p.o.), Negative (i.p.)
Reproductive Effects:	Parental NOEL: 100 mg/kg/day (Fertility study in rats) Reproductive/Fertility NOEL: 500 mg/kg/day (Fertility study in rats) Maternal NOEL: 100 mg/kg/day (Teratogenicity study in rats) Developmental NOEL: 100 mg/kg/day (Teratogenicity study in rats) Maternal NOEL: 2 mg/kg/day (Teratogenicity study in rabbits) Developmental NOEL: 2 mg/kg/day (Teratogenicity study in rabbits)

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Section 12: ECOLOGICAL INFORMATION

No data available on the environmental impact of this product.

Section 13: DISPOSAL CONSIDERATIONS

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
Shipping Name:	Not Regulated	Not Regulated	No Information Available	No Information Available	No Information Available
Hazard Class:	NA	NA			
UN Number:	NA	NA			
Package Group:	NA	NA			

There are no unreasonable risks (health, safety, or property), that this product would pose when transported in commerce.

Section 15: REGULATORY INFORMATION

OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):

Besivance™ (besifloxacin ophthalmic suspension) 0.6% is considered hazardous under the Occupational Safety & Health Administration's Hazard Communication Standard.

REACH:

This product is exempt from REACH requirements

TOXIC SUBSTANCE CONTROL ACT (TSCA):

All components of this product are listed on the TSCA inventory list, or are exempt from listing requirements.

SARA TITLE III (Superfund Amendments and Reauthorization Act):

- **SECTION 302 (Extremely Hazardous Substances):** NA
- **SECTION 311/312 (HAZARD CATEGORIES):** Acute
- **SECTION 313 (Toxic Chemicals):** NA

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 which exist. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb Incorporated nor any of its subsidiaries be liable for any special, incidental or consequential damages.