

Safety Data Sheet



Section 1: Identification

Product identifier

- Product Name** • **Besivance® Besifloxacin Hydrochloride Ophthalmic Suspension, 0.6% as base**
- Product Code** • AB44507; Core No. 445; NDC 24208-0446-05

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

- Recommended use** • Finished Pharmaceutical Product; Besivance® (besifloxacin ophthalmic suspension) 0.6%, is indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates.
- 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** • Acute Toxicity Oral 5
Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

- Hazard statements** • May cause eye irritation in sensitive individuals
May be harmful if swallowed

Precautionary statements

- Prevention** • Use only in accordance with label instructions and supplied prescribing information.

Wash thoroughly after handling.

- Response**
- IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of soap and water.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

- Storage/Disposal**
- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container.
Store protected from light and heat.
Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

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	0.01%	UN GHS: Skin Corr. 1B; Acute Tox. Oral 4; Acute Tox. Dermal 4; Aquatic Acute 1
Besifloxacin Hydrochloride	CAS:405165-61-9	0.6%	UN GHS: NDA
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 1%	UN GHS: NDA
Mannitol	CAS:69-65-8 EINECS:200-711-8	1% TO 5%	UN GHS: NDA
Poloxamer 407 Dimethacrylate	CAS:9003-11-6	< 1%	UN GHS: NDA
Polycarbophil	CAS:9003-97-8	< 1%	UN GHS: NDA
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Sodium hydroxide	CAS:1310-73-2 EINECS:215-185-5	5% TO 10%	UN GHS: Skin Corr. 1A
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Classification criteria not met

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 | <ul style="list-style-type: none">● Remove to fresh air. If signs/symptoms develop, get medical attention. |
| Skin | <ul style="list-style-type: none">● IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. |
| Eye | <ul style="list-style-type: none">● 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: Get medical advice/attention. |
| Ingestion | <ul style="list-style-type: none">● If swallowed, rinse mouth with water (only if the person is conscious) Call a physician or poison control center immediately. Individuals who have ingested the drug should be monitored for symptoms associated with exposure to beta-adrenergic blocking agents, as described in the supplemental information provided in Section 2 (Hazard Identification), including respiratory, cardiac, or cardiopulmonary reactions. |

Most important symptoms and effects, both acute and delayed

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Indication of any immediate medical attention and special treatment needed

Other information

- Refer to product prescribing information.

Section 5: Fire-Fighting Measures

Extinguishing media

- | | |
|---------------------------------------|--|
| Suitable Extinguishing Media | <ul style="list-style-type: none">● Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire. |
| Unsuitable Extinguishing Media | <ul style="list-style-type: none">● No data available |
| Firefighting Procedures | <ul style="list-style-type: none">● Fire fighters should wear complete protective clothing including self-contained breathing apparatus. |

Special hazards arising from the substance or mixture

- | | |
|---|--|
| Unusual Fire and Explosion Hazards | <ul style="list-style-type: none">● None known. |
| Hazardous Combustion Products | <ul style="list-style-type: none">● During a fire, thermal decomposition or combustion may generate irritating and highly toxic gases. |

Advice for firefighters

- No data available

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- | | |
|-----------------------------|--|
| Personal Precautions | <ul style="list-style-type: none">● 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. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8. No special precautions expected to be necessary if material is used under ordinary conditions and as recommended. Avoid any skin contact. |
| Emergency Procedures | <ul style="list-style-type: none">● No emergency procedures are expected to be necessary when used in accordance with product literature. |

Environmental precautions

- No data available on the environmental impact of this product.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- Use appropriate Personal Protective Equipment (PPE)
Avoid generating dust.
Wash away spilled liquid remainder with plenty of water.
For bulk material spills: 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.

Reference to other sections

- Refer to Section 8 - Exposure Controls/Personal Protection and Section 13 - Disposal Considerations.

Section 7 - Handling and Storage**Precautions for safe handling****Handling**

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

Conditions for safe storage, including any incompatibilities**Storage**

- Keep tightly closed. Store at room temperature 15-25°C (59-77°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

Special Packaging Materials

- Maintain product in original container only.

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
Sodium hydroxide (1310-73-2)	Ceilings	2 mg/m3 Ceiling	2 mg/m3 Ceiling	2 mg/m3 Ceiling	Not established
	TWAs	Not established	Not established	Not established	2 mg/m3 TWA

Exposure controls**Engineering Measures/Controls**

- Not required during normal clinical use. No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment**Pictograms****Respiratory**

- No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -organic vapor 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/Face

- No special personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event

Thermal hazards	of a bulk spill, wear appropriate protective clothing.
General Industrial Hygiene Considerations	<ul style="list-style-type: none"> • None known.
Environmental Exposure Controls	<ul style="list-style-type: none"> • Avoid contact with skin and eyes. Wash thoroughly with soap and water after handling. • No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Not relevant
Color	Opaque white to off-white.	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	= 1.01	Water Solubility	Not soluble in water
Viscosity	1500 Centipoise (cPs, cP) or mPas approximately		
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

- Stable under normal temperatures and pressures.

Chemical stability

- No data available

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- Consult physician regarding potential drug interactions.

Hazardous decomposition products

- During a fire, thermal decomposition or combustion may generate irritating and highly toxic gases.

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.

Components		
Edetate Disodium Dihydrate (< 1%)	139-33-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2 g/kg
Sodium chloride (< 1%)	7647-14-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3000 mg/kg; Irritation: Eye-Rabbit • 10 mg • Moderate irritation; Skin-Rabbit • 500 mg 24 Hour(s) • Mild irritation
Polycarbophil (< 1%)	9003-97-8	Acute Toxicity: Ingestion/Oral-Rat LD50 • 20 g/kg; Gastrointestinal:Other changes
Mannitol (1% TO 5%)	69-65-8	Acute Toxicity: Ingestion/Oral-Rat LD50 • 13500 mg/kg
Poloxamer 407 Dimethacrylate (< 1%)	9003-11-6	Acute Toxicity: Ingestion/Oral-Rat LD50 • 5700 mg/kg; Behavioral:Somnolence (general depressed activity); Gastrointestinal:Hypermotility, diarrhea
Sodium hydroxide (5% TO 10%)	1310-73-2	Acute Toxicity: Intraperitoneal-Mouse LD50 • 40 mg/kg
Benzalkonium Chloride (0.01%)	63449-41-2	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 150 mg/kg; Behavioral:Somnolence (general depressed activity); Blood:Hemorrhage

GHS Properties	Classification
Acute toxicity	UN GHS • Acute Toxicity - Oral 5
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)

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

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Skin

Acute (Immediate)

- Not expected to cause skin irritation.

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Eye

Acute (Immediate)

- May cause eye irritation in sensitive individuals.

Chronic (Delayed)

- 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)

- May cause nausea, diarrhea, anorexia, and dry mouth.

Chronic (Delayed)

- Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Carcinogenic Effects		
	CAS	NTP
Mannitol	69-65-8	Evidence of Carcinogenicity

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- Substance is readily biodegradable.

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
Edetate Disodium Dihydrate	139-33-3	Yes	Yes	Yes
Benzalkonium Chloride	63449-41-2	Yes	Yes	Yes
Besifloxacin Hydrochloride	405165-61-9	No	No	No
Polycarbophil	9003-97-8	No	No	No
Mannitol	69-65-8	Yes	Yes	Yes
Poloxamer 407 Dimethacrylate	9003-11-6	Yes	No	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Sodium hydroxide	1310-73-2	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada**Labor****Canada - WHMIS - Classifications of Substances**

• Mannitol	69-65-8	Uncontrolled product according to WHMIS classification criteria
• Edetate Disodium Dihydrate	139-33-3	Uncontrolled product according to WHMIS classification criteria (including 3.5%)
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium hydroxide	1310-73-2	E (including 0.04% in aqueous solution, 0.08%, 0.4% in aqueous solution, 2%, 2.5%, 4% in aqueous solution, 5%, 10%, 16%, 20%, 40%, 50% in aqueous solution, 8.7N)
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Mannitol	69-65-8	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium hydroxide	1310-73-2	1 %
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed

• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

Europe

Other

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

• Mannitol	69-65-8	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Xn; R21/22 C; R34 N; R50
• Sodium hydroxide	1310-73-2	C; R35
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

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

• Mannitol	69-65-8	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium hydroxide	1310-73-2	5%≤C: C; R:35 2%≤C<5%: C; R:34 0.5%≤C<2%: Xi; R:36/38
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

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

• Mannitol	69-65-8	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	C N R:21/22-34-50 S:(2)-36/37/39-45-61
• Sodium hydroxide	1310-73-2	C R:35 S:(1/2)-26-37/39-45
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

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

• Mannitol	69-65-8	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	S:(2)-36/37/39-45-61
• Sodium hydroxide	1310-73-2	S:(1/2)-26-37/39-45
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

United States

Environment

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

• Mannitol	69-65-8	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium hydroxide	1310-73-2	1000 lb final RQ; 454 kg final RQ
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Mannitol	69-65-8	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

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

• Mannitol	69-65-8	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

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

• Mannitol	69-65-8	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Sodium hydroxide	1310-73-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

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

• Mannitol	69-65-8	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed

• Sodium hydroxide	1310-73-2	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Water	7732-18-5	Not Listed
• Polycarbophil	9003-97-8	Not Listed
• Poloxamer 407 Dimethacrylate	9003-11-6	Not Listed
• Besifloxacin Hydrochloride	405165-61-9	Not Listed

Section 16 - Other Information

Last Revision Date

- 05/May/2015

Preparation Date

- 05/May/2015

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