

Latanoprost Ophthalmic Solution, 0.005%

MATERIAL SAFETY DATA SHEET

Effective Date: 3/15/11 Supersedes: None

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

Product Name: Latanoprost Ophthalmic Solution, 0.005%
Product Code(s): AB46395
NDC No(s): 24208-463-25 (2.5 mL)
Intended Use: Pharmaceutical product used for glaucoma
Chemical Family: Mixture

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 (GHS)

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: Use only in accordance with label instructions and supplied prescribing information.
Avoid release to the environment.
Keep out of reach of children.

PRECAUTIONS:**Caution! Pharmacologically Active**

Latanoprost Ophthalmic Solution is indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Latanoprost Ophthalmic Solution should be used with caution in patients with a history of intraocular inflammation (iritis/uveitis) and should generally not be used in patients with active intraocular inflammation. Refer to product prescribing information.

Do Not Use: If there exists hypersensitivity to any ingredient in this product.

Section 2: HAZARDS IDENTIFICATION (cont.)

WARNING: Contact lenses should be removed prior to administration of Latanoprost Ophthalmic Solution, and may be reinserted 15 minutes after administration.

WARNING: *Keep out of reach of children.*

Use only in accordance with product prescribing information.

POTENTIAL HEALTH EFFECTS

EYE:

May cause eye irritation in sensitive individuals.

SKIN:

Not expected to cause skin irritation.

INGESTION:

May cause gastrointestinal irritation or other disturbances.

INHALATION:

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

CHRONIC HEALTH EFFECTS

May cause nausea, abdominal discomfort, dizziness, headache, fatigue, sweating, change in eye color, change in eyelash color, and change in eyelid color.

CARCINOGENICITY:

NTP: No component of this product, present at levels greater than or equal to 0.1%, is identified as a known or anticipated carcinogen by NTP.

IARC: No component of this product, present at levels greater than or equal to 0.1%, is identified as a known or anticipated carcinogen by IARC.

OSHA: No component of this product, present at levels greater than or equal to 0.1%, is identified as a known or anticipated carcinogen by OSHA.

MEDICAL CONDITIONS AGGRAVATED BY OVER EXPOSURE:

This product should not be used in patients with a history of hypersensitivity to latanoprost, benzalkonium chloride or any other ingredients in this product. Refer to the product insert for additional information.

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Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

CAS #	Chemical Identity	Concentration, % W/W	EINECS / ELINCS #
130209-82-4	Latanoprost	0.005	NA
10049-21-5	Sodium Phosphate Monobasic, Monohydrate	Proprietary	NA
7647-14-5	Sodium Chloride	Proprietary	231-598-3
7558-79-4	Sodium Phosphate, Dibasic	Proprietary	231-448-7
8001-54-5	Benzalkonium Chloride	0.02	NA
7732-18-5	Purified Water	Proprietary	231-791-2

Section 4: FIRST AID MEASURES

EYES:

If discomfort or irritation develops, immediately discontinue product use and contact your eye care professional. For accidental or non-therapeutic applications, flush eyes with copious amounts of water for at least 15 minutes. Get medical attention.

SKIN:

Immediately wash skin with soap and flush with copious amounts of water for at least 15 minutes while removing contaminated clothing. Wash clothing separately before reuse. 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. 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.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

For guidance, refer to the product insert.

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.

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Section 5: FIRE FIGHTING MEASURES (cont.)

HAZARDOUS COMBUSTION PRODUCTS:

Emits hazardous products of combustion.

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. 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.

METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

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 thoroughly with warm water and soap after handling.

STORAGE:

Protect from light. Store product as directed by product packaging.

Shelf Life: Expiration date is listed on each package. **Keep out of reach of children.**

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Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

CONTROL PARAMETERS:

OCCUPATIONAL EXPOSURE LIMITS / GUIDELINES

CAS #	COMPONENT NAME	OSHA PEL TWA /STEL	ACGIH TLV TWA /STEL	NIOSH REL TWA /STEL	IRELAND TWA /STEL	HSE TWA /STEL	UNITS
130209-82-4	Latanoprost	NE NE	NE NE	NE NE	NE NE	NE NE	NA
10049-21-5	Sodium Phosphate Monobasic, Monohydrate	NE NE	NE NE	NE NE	NE NE	NE NE	NA
7647-14-5	Sodium Chloride	NE NE	NE NE	NE NE	NE NE	NE NE	NA
7558-79-4	Sodium Phosphate, Dibasic	NE NE	NE NE	NE NE	NE NE	NE NE	NA
8001-54-5	Benzalkonium Chloride	NE NE	NE NE	NE NE	NE NE	NE NE	NA
7732-18-5	Purified Water	NE NE	NE NE	NE NE	NE NE	NE NE	NA

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

* Total Dust

** Respirable Fraction

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

TLV: Threshold Limit Value

OEL: 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

PEL: Permissible Exposure Limit

I: Measured as inhalable fraction of the aerosol

ENGINEERING CONTROLS:

Not required during normal clinical use. Local exhaust ventilation should be provided when handling bulk product.

RESPIRATORY PROTECTION:

Not required during normal clinical use.

Where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with HEPA and organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. 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.

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 State:	Liquid
Color:	Colorless to slightly yellow
Odor:	No distinct odor
Odor Threshold:	Not determined
pH-Value:	6.7
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):	1.0073
Solubility:	Very soluble in acetonitrile and freely soluble in acetone, ethanol, ethyl acetate, isopropanol, methanol and octanol. Practically insoluble in water.
Partition Coefficient:	Not applicable
Auto-Ignition Temperature:	Not determined
Decomposition Temperature:	Not determined
Osmolality:	267 mOsmol/kg
Viscosity:	Not determined

Section 10: STABILITY AND REACTIVITY

GENERAL:

Stable

CONDITIONS TO AVOID:

Extreme heat or cold.

INCOMPATIBLE MATERIALS:

Keep away from strong oxidizing materials. Avoid exposure to or contact with extreme temperatures, light, and any identified incompatible chemicals.

HAZARDOUS POLYMERIZATION:

Will not occur.

HAZARDOUS DECOMPOSITION PRODUCTS:

When exposed to extreme temperatures, this material may generate carbon monoxide, carbon dioxide, and nitrogen oxides.

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Section 11: TOXICOLOGICAL INFORMATION

ACTIVE INGREDIENT(S):

RTECS No.: MJ9669550

Latanoprost

Toxicity Data: ORL-RAT LD50: > 50 MG/KG

Mode of action:

Latanoprost is a prostanoid selective FP receptor agonist that is believed to reduce the intraocular pressure (IOP) by increasing the outflow of aqueous humor. Studies in animals and man suggest that the main mechanism of action is increased uveoscleral outflow.

Chronic Toxicity:

Apart from ocular irritation and conjunctival or episcleral hyperemia, the ocular effects of latanoprost administered at high doses are not known. Intravenous administration of large doses of latanoprost in monkeys has been associated with transient bronchoconstriction; however, in 11 patients with bronchial asthma treated with latanoprost, bronchoconstriction was not induced. Intravenous infusion of up to 3 µg/kg in healthy volunteers produced mean plasma concentrations 200 times higher than during clinical treatment and no adverse reactions were observed. Intravenous dosages of 5.5 to 10 µg/kg caused abdominal pain, dizziness, fatigue, hot flushes, nausea and sweating.

Teratogenicity:

Latanoprost (Xalatan) is a prostaglandin F2-alpha analog used in the treatment of intraocular hypertension. Preclinical studies reported by the manufacturer (Pharmacia Corporation, Peapack NJ) indicate that 25% of rabbits treated during pregnancy with 80 times the human dose had no viable fetuses at term. The highest rabbit dose at which there were no adverse embryo effects was 15 times the human dose. No other information was presented on reproductive or lactation effects. Prostaglandin F2-alpha has abortifacient and luteolytic effects and it is not surprising that the analog would show adverse effects at high dose.

Reproduction Toxicology:

See Teratogenicity above. Impaired fertility demonstrated in dogs. Not listed as a developmental toxicant by The State of California, as of June 9, 2006.

Mutagenicity:

Latanoprost is not mutagenic in bacteria, mouse lymphoma or in mouse micronucleus tests (Prod Info Xalatan(R), Latanoprost, 1999).

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Section 11: TOXICOLOGICAL INFORMATION (cont.)

INACTIVE INGREDIENT(S):

RTECS No.: VZ4725000

Sodium Chloride

Toxicity Data: ORL-RAT LD50: 3000 MG/KG

RTECS No.: WC4500000

Sodium Phosphate, Dibasic

Toxicity Data: ORL-RAT LD50: 17 GM/KG

RTECS No.: BO3150000

Benzalkonium Chloride

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

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

Section 12: ECOLOGICAL INFORMATION

No data is available on the environmental impact of this product. Avoid release to the environment.

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

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

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Section 15: REGULATORY INFORMATION

OSHA HAZARD COMMUNICATION STANDARD (29 CFR 1910.1200):

Latanoprost Ophthalmic Solution is considered non-hazardous under the Occupational Safety & Health Administration's Hazard Communication Standard.

TOXIC SUBSTANCE CONTROL ACT (TSCA):

CAS# 7647-14-5 is listed on the TSCA Inventory.
CAS# 7558-79-4 is listed on the TSCA Inventory.
CAS# 7732-18-5 is listed on the TSCA Inventory.

REACH:

CAS #	REACH	SVHC	SIN
130209-82-4	NR	No	No
10049-21-5	PR	No	No
7647-14-5	PR	No	No
7558-79-4	PR	No	No
8001-54-5	PR	No	No
7732-18-5	PR	No	No

PR: Pre-Registered
NR: Not Registered
SVHC: Substance of Very High Concern
SIN: Substitute It Now

SARA TITLE III (Superfund Amendments and Reauthorization Act):

- **SECTION 302 (Extremely Hazardous Substances):** NA
- **SECTION 311/312 (HAZARD CATEGORIES):** NA
- **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.