

## SAFETY DATA SHEET

1. Identification

**Product Identifier:** Latanoprost Ophthalmic Solution, 0.005%

**Synonyms:** Isopropyl-(Z)-7[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate

**National Drug Code (NDC):** 17478-625-12

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

**Physical Hazards:** Not classifiable.  
**Health Hazards:** Not classifiable.  
**Symbol(s):** None.  
**Signal Word:** None.  
**Hazard Statement(s):** None.  
**Precautionary Statement(s):** None.  
**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Latanoprost	130209-82-4	Isopropyl-(Z)-7[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(3R)-3-hydroxy-5-phenylpentyl]cyclopentyl]-5-heptenoate	C <sub>26</sub> H <sub>40</sub> O <sub>5</sub>	432.58	0.005%

\* The formula also contains Benzalkonium Chloride, 0.02% as a preservative. Inactive Ingredients are Sodium Chloride, Sodium Dihydrogen Phosphate Monohydrate, Disodium Hydrogen Phosphate Anhydrous and Water for Injection.

**4. First Aid Measures**

<b>Ingestion:</b>	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
<b>Eye Contact:</b>	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Contact:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	No data available.
<b>Medical Conditions Aggravated by Exposure:</b>	No data available.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

**5. Firefighting Measures**

<b>Suitable Extinguishing Media:</b>	Use water, carbon dioxide, dry chemical or foam as necessary.
<b>Unsuitable Extinguishing Media:</b>	Not determined.

**Specific Hazards Arising from the Chemical:**

- Hazardous Combustion Products:** Carbon dioxide, carbon monoxide.
- Other Specific Hazards:** Fine particles may fuel fires and/or explosions.
- Special Protective Equipment/ Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

**6. Accidental Release Measures**

- Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
- Personal Protective Equipment:** For personal protection see section 8.
- Methods for Cleaning Up:** The source of the spill should be contained if it is safe to do so. Collect spill with absorbent material and clean the area of the spill thoroughly. Waste should be placed in appropriate waste disposal container. Clean up should be performed only by trained personnel who should be wearing appropriate protective equipment. All additional personnel should be evacuated from the spill area.
- Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situation immediately. Clean up operations should only be undertaken by trained personnel.
- Environmental Precautions:** Environmental properties have not been thoroughly investigated. Release to the environment should be avoided.
- Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

**7. Handling and Storage**

- Precautions for Safe Handling:** Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
- Conditions for Safe Storage, Including Any Incompatibilities:** Store according to label and/or product insert information. Store between 2°C and 8°C.
- Specific End Use:** Pharmaceuticals.

**8. Exposure Controls/Personal Protection**

**Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits
Latanoprost	Pfizer OEL: 0.7 µg/m <sup>3</sup> , 8 Hour TWA.

## SDS: Latanoprost Ophthalmic Solution, 0.005%

<b>Engineering Controls:</b>	Engineering controls should be used as the primary means to control exposures.
<b>Respiratory Protection:</b>	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
<b>Eyes Protection:</b>	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Hand Protection:</b>	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Skin Protection:</b>	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

### 9. Physical and Chemical Properties

<b>Physical State/Color:</b>	Clear, colorless to slightly yellow liquid.
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	6.7.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	No data available.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

**10. Stability and Reactivity**

**Reactivity:** No data available.

**Chemical Stability:** Stable under recommended storage conditions.

**Possibility of Hazardous Reactions:** No data available.

**Conditions to Avoid (e.g., static discharge, shock, or vibration):** Fine particles (dust, mists) may cause fire and/or explosions. Keep away from strong oxidizers.

**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers.

**Hazardous Decomposition Products:** No data available.

**11. Toxicological Information**

**Information on the Likely Routes of Exposure:**

**Inhalation:** No data available.

**Ingestion:** Accidental ingestion may cause effects similar to those seen in clinical cases.

**Skin Contact:** Not expected to cause skin irritation.

**Eye Contact:** May cause eye irritation.

**Known Clinical Effects:** Nausea, abdominal discomfort, headache, dizziness, sweating, fatigue, change in eye color, change in eyelash color, change in eyelid color.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

**Acute Toxicity:**

Compound	Species	Route	End Point	Dose
Latanoprost	Rat	Oral	LD <sub>50</sub>	>50 mg/kg
Latanoprost	Mouse	Oral	LD <sub>50</sub>	>50 mg/kg
Latanoprost	Rat	Intravenous	LD <sub>50</sub>	>2 mg/kg
Sodium Chloride	Rat	Oral	LD <sub>50</sub>	3,000 mg/kg
Sodium Chloride	Mouse	Oral	LD <sub>50</sub>	4,000 mg/kg
Benzalkonium Chloride	Rat	Oral	LD <sub>50</sub>	240 mg/kg
Sodium Phosphate, dibasic	Rat	Oral	LD <sub>50</sub>	17 mg/kg

**Irritation/Sensitization:**

Compound	Species	Study Type	Severity
Latanoprost	Rabbit	Skin irritation	Slight
Latanoprost	Rabbit	Eye irritation	No effect
Latanoprost	Guinea Pig	Skin sensitization - GPMT	Negative
Latanoprost	Mouse	Antigenicity-Passive cutaneous anaphylaxis	Negative
Latanoprost	Guinea Pig	Antigenicity-Passive cutaneous anaphylaxis	Negative
Sodium Chloride	Rabbit	Skin irritation	Mild
Sodium Chloride	Rabbit	Eye irritation	Moderate
Benzalkonium Chloride	Rabbit	Skin irritation	Moderate
Benzalkonium Chloride	Rabbit	Eye irritation	Severe
Sodium Phosphate, dibasic	Rabbit	Skin irritation	Mild
Sodium Phosphate, dibasic	Rabbit	Eye irritation	Mild

**Repeated Dose Toxicity:**

Compound	Species	Route	End Point	Dose	Duration	Target Organ
Latanoprost	Rat	Oral	NOAEL	0.2 mg/kg/day	28 Days	None identified
Latanoprost	Rat	Oral	NOAEL	0.2 mg/kg/day	13 Weeks	None identified
Latanoprost	Dog	Intravenous	NOAEL	0.2 mg/kg/day	13 Weeks	None identified
Latanoprost	Rat	Oral	NOAEL	0.2 mg/kg/day	2 Years	None identified

**Reproduction & Development Toxicity:**

Compound	Study Type	Species	Route	Type	Dose	Effect(s)
Latanoprost	Fertility & Embryonic Development	Rabbit	Intravenous	NOAEL	0.001 mg/kg/day	Embryotoxicity
Latanoprost	Reproductive & Fertility	Rat	Intravenous	NOAEL	0.035 mg/kg/day	Paternal toxicity/ Not Teratogenic
Latanoprost	Parental & Postnatal Development	Rat	Intravenous	NOAEL	0.01 mg/kg/day	No effects at Maximum dose
Latanoprost	Embryo/Fetal Development	Rat	Intravenous	NOAEL	0.05 mg/kg/day	Paternal toxicity/ Not Teratogenic

**Genetic Toxicity:**

Compound	Study Type	Cell Type/Organism	Results
Latanoprost	Bacterial Mutagenicity (Ames)	Bacteria	Negative
Latanoprost	<i>In Vitro</i> Mammalian Cell Mutagenicity	Mouse Lymphoma	Negative
Latanoprost	<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Positive with activation
Latanoprost	<i>In Vivo</i> Unscheduled DNA Synthesis	Rat Hepatocyte	Negative
Latanoprost	<i>In Vivo</i> Micronucleus	Mouse Bone Marrow	Negative

**Acute Toxicity – Dermal:**

No data available.

**Acute Toxicity – Inhalation:**

No data available.

**Corrosivity:**

No data available.

**Toxicokinetics/Metabolism:**

No data available.

<b>Target Organ Effects:</b>	No data available.
<b>Carcinogenicity:</b>	Not expected to be carcinogenic.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
<b>Mutagenicity:</b>	No data available.
<b>Aspiration Hazard:</b>	Based on available data, the classification criteria are not met.

**12. Ecological Information**

**Ecotoxicity**

<b>Aquatic:</b>	No data available.
<b>Terrestrial:</b>	No data available.
<b>Persistence and Degradability:</b>	No data available.
<b>Bioaccumulative Potential:</b>	No data available.
<b>Mobility in Soil:</b>	No data available.
<b>Mobility in Environment:</b>	No data available.
<b>Other Adverse Effects:</b>	No data available.

**13. Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

**14. Transport Information**

<b>UN Number:</b>	Not applicable.
<b>UN Proper Shipping Name:</b>	Not applicable.
<b>Transport Hazard Class(es):</b>	Not applicable.
<b>Packing Group:</b>	Not applicable.
<b>Department of Transportation:</b>	Not regulated as a hazardous material.
<b>International Air Transport Association (IATA):</b>	Not regulated as a dangerous good.
<b>International Maritime Dangerous Good (IMDG):</b>	Not regulated as a dangerous good.

**15. Regulatory Information**

**US Federal Regulations:**

**Toxic Substance Control Act (TSCA):** Listed.

**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.

**SARA 313:** Not listed.  
**SARA 302:** Not listed.

**State Regulations**

**California Proposition 65:** Not listed.

**16. Other Information**

**Revision Date:** 05/01/2015

**Revision Number:** 1

**Disclaimer:** This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.