MSDS: LATANOPROST OPHTHALMIC SOLUTION 0.005%

Manufacturer: Akorn
1925 W. Field Court Suite 300
Lake Forest, IL 60045

Contact Telephone: 1-800-932-5676
Email: customer.service@akorn.com

Section 1 - IDENTIFICATION

Common/Trade Name: LATANOPROST OPHTHALMIC SOLUTION 0.005%

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

Chemical Formula: $C_{26}H_{40}O_5$

Category: Prescription Only.

Section 2 – HAZARD(S) IDENTIFICATION

Routes of Entry: For external use only. Not for injection.

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Carcinogenicity: Not expected to be carcinogenic.

NTP: Not listed as carcinogen.

IARC: Not listed as carcinogen.

OSHA Regulated: Not listed as carcinogen.

Additional Hazard Information:

Short Term: May cause eye irritation. Not expected to cause skin irritation. Accidental ingestion may cause effects similar to those seen in clinical cases.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

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

Section 3 – COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS#	Amount
Latanoprost	130209-82-4	50 µg/mL
Benzalkonium Chloride	8001-54-5	0.2 mg/mL

Inactive ingredients: sodium chloride, sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate anhydrous and water for injection (qs).

Section 4 – FIRST AID MEASURES

Eyes: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Vomiting should not be induced unless directed by medical personnel. Seek medical attention immediately.

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Section 5 – FIRE FIGHTING MEASURES

Flash Point:	NA
Auto ignition:	NA
Lower Explosion Limit:	NA
Upper Explosion Limit:	NA
General Hazard:	Fine particles may fuel fires and/or explosions.
Fire Fighting Instructions:	NA
Extinguishing Media:	Use water spray, carbon dioxide, dry chemical.
Fire Fighting Equipment:	Appropriate protective equipment should be worn during all fire fighting activities, including self-contained breathing apparatus.
Hazardous Combustion Products:	Carbon dioxide, carbon monoxide

Section 6 – ACCIDENTAL RELEASE MEASURES

Clean-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.

Section 7 – HANDLING AND STORAGE

Precautions: NA

General Handing: Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational or environmental release. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors and appropriate filtration systems.

Storage Conditions: Store between 2°C and 8°C

Section 8 –EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed in this section.

Personal Protective Equipment

Eye Protection: Wear safety glasses or goggles if eye contact is possible.

Hand Protection: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory Protection: If the applicable Occupational Exposure Limit (OEL) is exceeded appropriate respirator with a protection factor sufficient to control exposures to below OEL should be worn.

Skin Protection: Impervious protective clothing is recommended if skin contact is possible and for bulk processing operations.

Exposure Limits:

Compound	Issuer	Type	OEL
Latanoprost	Pfizer	TWA-8hr	0.7 µg/m^3

Section 9 – PHYSICAL/CHEMICAL CHARACTERISTICS

Physical Form/ Appearance:	Clear, colorless to slightly yellow solution.
Boiling Point/Boiling Range:	NA
Melting Point/Melting Range:	NA
Freezing Point:	NA
Vapor Pressure:	NA
Relative Vapor Density:	NA
Percent Volatiles:	NA
pH:	NA
Molecular Weight:	NA
Solvent Solubility:	NA
Latex Free:	NA
Physical State:	Liquid

Section 10 – STABILITY AND REACTIVITY

Reactivity:	NA
Chemical Stability:	Stable under normal conditions.
Possibility of Hazardous Reactions:	NA
Conditions to Avoid:	Fine particles (dust, mists) may cause fire and/or explosions. Keep away from strong oxidizers.
Hazardous Polymerization:	Does not occur.
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers.

Section 11 – TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity:

Comment: The greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Latanoprost

Species	Route	End Point	Dose
Rat	Oral	LD50	>50 mg/kg
Rat	Intravenous	LD50	> 2 mg/kg
Mouse	Oral	LD50	>50 mg/kg

Sodium Chloride

Species	Route	End Point	Dose
Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Benzalkonium Chloride

Species	Route	End Point	Dose
Rat	Oral	LD50	240 mg/kg

Sodium Phosphate, dibasic

Species	Route	End Point	Dose
Rat	Oral	LD50	17 mg/kg

Irritation/Sensitization

Latanoprost

Species	Study Type	Severity
Rabbit	Skin Irritation	Slight
Rabbit	Eye Irritation	No Effect
Guinea Pig	Skin Sensitization –GPMT	Negative
Mouse	Antigenicity-Passive cutaneous anaphylaxis	Negative
Guinea Pig	Antigenicity-Passive cutaneous anaphylaxis	Negative

Sodium Chloride

Species	Study Type	Severity
Rabbit	Skin Irritation	Mild
Rabbit	Eye Irritation	Moderate

Beznalkonium Chloride

Species	Study Type	Severity
Rabbit	Skin Irritation	Moderate
Rabbit	Eye Irritation	Severe

Sodium Phosphate, dibasic

Species	Study Type	Severity
Rabbit	Skin Irritation	Mild
Rabbit	Eye Irritation	Mild

Repeated Dose Toxicity

Latanoprost

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

Reporoduction & Development Toxicity

Latanoprost

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

Genetic Toxicity

Latanoprost

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

Signs & Symptoms of Exposure & Overexposure: Refer to Section 2.

Medical Conditions Aggravated by Accidental Exposure: NA

Section 12 – ECOLOGICAL INFORMATION

Ecotoxicity : Data not yet available.

Biodegradable : Data not yet available.

Environmental Overview : Environmental properties have not been thoroughly investigated. Release to the environment should be avoided.

Section 13 – DISPOSAL INFORMATION

Disposal Procedure: Dispose of waste in accordance to all applicable laws and regulations. Member state specific and community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational and environmental releases. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent the environmental release. This may include destructive techniques for waste and wastewater.

Section 14 – TRANSPORT INFORMATION

UN/NA Nimber: NA

U.S. DOT Hazard Class: NA

Proper Shipping Name: NA

Shipping Label: NA

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15 – REGULATORY INFORMATION

FDA (Food & Drug Administration): NA

TSCA (Toxic Substance Control Act): Listed

HMIS (Hazardous Materials Information System (USA)): NA

WHMIS (Workplace Hazardous Materials): Hazard Class not required.

EU Indication of Danger: Not Classified

OSHA Label: Non-hazardous in accordance with international standards for workplace safety.

Section 16 – OTHER INFORMATION

Date of preparation or last revision: 08-13

Key to Abbreviations:

NA = Not Available