



SAFETY DATA SHEET

Latanoprost ophthalmic solution 0.005%

1. Product and Company Information

Product Identifier: Latanoprost Ophthalmic Solution 0.005%
Synonyms: None
National Drug Code: 70069-421-01
Recommended Use: Ophthalmic solution
Company: Somerset Therapeutics LLC
Hollywood, FL 33024
Contact Telephone: 1800-417-9175
E-Mail:
Emergency Phone Number: 1800-417-9175

2. Hazardous(s) Identification

Physical Hazards: None
Health Hazards: None
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: None
Supplementary Information: Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System

3. Composition and Information on Ingredients

Component	CAS	Percentage
Latanoprost	130209824	<0.1
Benzalkonium chloride NF	8001-54-5	*
Sodium Phosphate Monobasic, monohydrate	10049-21-5	*
Sodium chloride USP	7647-14-5	*
Sodium phosphate, dibasic	7558-79-4	*
Water	7732-18-5	*

Additional Information: * Proprietary Ingredient(s) indicated as hazardous have been assessed under standards for work place safety.

4. First Aid Measures

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

Skin: Remove contaminated clothing. Flush area with lots amount of water and wash use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

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

Symptoms and effects of exposure: For information on potential signs and symptoms of exposure See section 2 hazards identification and/ or Section 11- Toxicological information.

5. Fire-Fighting Measures

Extinguishing Media: Use carbon dioxide, dry chemical or water spray.

Hazardous Combustion Products: Carbon dioxide, carbon monoxide

Fire Fighting Procedures: During all firefighting activities wear appropriate protective equipment including self-contained breathing apparatus

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/ explosions

6. Accidental Release Measures

Healthy and safety precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see section 8). Minimize exposure.

Measures for cleaning and collecting: contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures of environmental protections: Place waste in an appropriate labelled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional consideration for large spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately clean-up operations should only be undertaken by trained personnel.

7. Handling and Storage:

General Handling: Avoid contact with eyes, skin and clothing. Avoid breathing vapour or mist. When handling, use appropriate personal protective equipment (see section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or

environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems of other equivalent controls

Storage Conditions: Store unopened bottle(s) under refrigeration at 2° to 8°C (36° to 46°F). During shipment to the patient, the bottle may be maintained at temperatures up to 40°C (104°F) for a period not exceeding 8 days. Once a bottle is opened for use, it may be stored at room temperature up to 25°C (77°F) for 6 weeks. Protect from light.

8. Exposure Controls / Personal Protection

Refer to available public information for specific member state occupational exposure limits.

Latanoprost

Pfizer OEL TWA-8 Hr: 0.7µg/m³

Sodium chloride

Latvia OEL – TWA Listed

Lithuania OEL – TWA Listed

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 above in this section.

Environmental Exposure controls:

Refer to specific member state legislation for requirements under community environmental legislation.

Personal protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

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

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

Skin: Impervious protective clothing is 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, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. Physical and Chemical Properties

Physical state	Liquid
Molecular formula	Mixture
Color	Colorless to light yellow
Molecular weight	Mixture

10. Stability and Reactivity

Stability:	Stable at normal conditions
Conditions to Avoid:	Fine particles (Such as dust and mists) may fuel fires/explosions

11. Toxicological Information

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

Acute Toxicity: (Species, Route, End point, Dose)**Latanoprost**

Rat Oral LD 50 > 50 mg/kg
Rat Intravenous LD 50 > 2 mg/kg
Mouse Oral LD 50 > 50 mg/kg

Sodium Chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD 50 4000 mg/kg

Benzalkonium chloride

Rat Oral LD 50 240 mg/kg

Sodium phosphate dibasic

Rat Oral LD 50 17g/kg

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.

Irritation / Sensitization: (Study type, Species, Severity)

Latanoprost

Skin irritation Rabbit Slight
Eye irritation Rabbit No effect
Skin Sensitization – GMPT Guinea Pig Negative
Antigenicity – Passive Cutaneous anaphylaxis Mouse negative
Antigenicity – Passive cutaneous anaphylaxis Guinea Pig Negative

Sodium chloride

Eye irritation	Rabbit	Moderate
Skin irritation	Rabbit	Mild

Benzalkonium chloride

Skin irritation	Rabbit	Moderate
Eye irritation	Rabbit	Severe

Sodium phosphate, Dibasic

Eye irritation	Rabbit	Mild
Skin irritation	Rabbit	Mild

Repeated dose Toxicity: (Duration, Species, Route, Dose, End point, target organ)**Latanoprost**

28 Day(s) Rat Oral 0.2 mg/kg/day NOAEL None identified
13 Week(s) Rat Oral 0.2 mg/kg/day NOAEL None identified
13 Week(s) Dog Intravenous 0.001 mg/kg/day NOAEL None identified

Reproduction and development toxicity: (Study type, Species, Route, Dose, End point, Effect(s))**Latanoprost**

Fertility and Embryonic Development Rabbit intravenous 0.001 mg/kg/day NOAEL
Embryo toxicity
Reproductive and fertility Rat Intravenous 0.035mg/kg/day NOAEL Paternal toxicity,
Not teratogenic
Prenatal and post-natal development Rat intravenous 0.01mg/kg/day NOAEL no effects
at maximum dose.
Embryo/ Fetal development Rat Intravenous 0.05mg/kg/day NOAEL Paternal toxicity,
Not teratogenic

Genetic Toxicity: (Study type, Cell Type/ Organism, Result)**Latanoprost**

Bacterial mutagenicity (Ames) bacteria Negative
In vitro Mammalian cell mutagenicity Mouse Lymphoma Negative
In vitro Chromosomal Aberration Human Lymphocytes Positive without activation.
In Vivo Unscheduled DNA Synthesis Rat Hepatocyte Negative
In Vivo Micronucleus Mouse bone marrow Negative

Carcinogenicity: (Duration, Species, Route, Dose, End point, Effect(s))**Latanoprost**

80 Month(s) Mouse Oral 0.2 mg/kg/day NOAEL Not Carcinogenic
2 Year(s) Rat Oral 0.2 mg/kg/day NOAEL Not Carcinogenic

Carcinogen status:

None of the components of this formulation are listed as a carcinogen by IRAC, NTP or OSHA

12. Ecological Information

Environmental overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. Disposal Conditions

Disposal Procedures : Dispose of waste in accordance with 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 exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

14. Transportation Information

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

15. Regulatory Information

Eu Indication of danger : Not Classified

OSHA Label:

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

Canada – WHMIS: Classifications

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and MSDS contains all of the information required by CPR

Latanoprost

Standard for the uniform Scheduling for drugs and Poisons: Schedule 4

Sodium phosphate Monobasic, Monohydrate Australia (AICS): Listed

Benzalkonium chloride

Australia (AICS): Listed

Standard for the Uniform Scheduling Schedule 5
for Drugs and poisoning: Schedule 6

Sodium Chloride

Inventory – United states TSCA- Sec. 8(b)

Australia (AICS): Listed

EU EINECS/ELINCS List: 231-598-3

Sodium phosphate, dibasic

CERCLA/SARA Hazardous substances 2270kg final RQ

And their reportable quantities: 5000 lb final RQ

Inventory – United states TSCA-sect. 8(b) Listed

Australia (AICS): Listed

EU EINECS/ELINCS List: 231-448-7



Water

Inventory – United states TSCA- Sec. 8(b) Listed

Australia (AICS): Listed

REACH – Annex iv – Exemptions from obligations of register: present

EU EINECS/ELINCS List: 231-791-2

16. Other Information

Legend: NE- Not Established

Revision Date: 02/29/2020

Revision Number: 01

Disclaimer: As of the date of issuance, we are providing available information relevant to the handling of this material. All information contained herein is offered with the good faith belief that it is accurate. In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.