



# SAFETY DATA SHEET

Revision date: 31-Mar-2016

Version: 2.1

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## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Latanoprost Ophthalmic Solution (Greenstone LLC)

**Trade Name:** Not applicable

**Chemical Family:** Mixture

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used for glaucoma

### Details of the Supplier of the Safety Data Sheet

Greenstone LLC  
100 Route 206 North  
Peapack, NJ 07977  
800-435-7095

**Emergency telephone number:**  
CHEMTREC (24 hours): 1-800-424-9300

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification:** Not classified as hazardous

### Label Elements

**Signal Word:** Not required

**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

**Note:** No data available  
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Latanoprost	130209-82-4	Not Listed	Repr. 2 (H361d)	<0.1
Benzalkonium chloride	8001-54-5	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium Phosphate Monobasic, Monohydrate	10049-21-5	Not Listed	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*

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Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

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

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. 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.

#### Most Important Symptoms and Effects, Both Acute and Delayed

**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.

**Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

#### Special Hazards Arising from the Substance or Mixture

**Hazardous Combustion Products:** Carbon dioxide, carbon monoxide

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

#### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

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**Measures for Cleaning / Collecting:**

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**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

**Precautions for Safe Handling**

Avoid contact with eyes, skin and clothing. Avoid breathing vapor 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 or other equivalent controls.

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

Refer to available public information for specific member state Occupational Exposure Limits.

**Latanoprost**

**Manufacturer OEL:** 0.7ug/m<sup>3</sup>

**Sodium chloride**

**Latvia OEL - TWA** 5 mg/m<sup>3</sup>

**Lithuania OEL - TWA** 5 mg/m<sup>3</sup>

**Exposure Controls**

**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.

**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

**Color:**

Colorless to light yellow

**Odor:**

No data available.

**Odor Threshold:**

No data available.

**Molecular Formula:**

Mixture

**Molecular Weight:**

Mixture

**Solvent Solubility:**

No data available

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Water Solubility:** No data available  
**pH:** No data available.  
**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available.  
**Partition Coefficient: (Method, pH, Endpoint, Value)**

#### Latanoprost

Predicted 7.4 Log D 3.65

#### Water

No data available

#### Sodium Phosphate Monobasic, Monohydrate

No data available

#### Sodium chloride

No data available

#### Benzalkonium chloride

No data available

#### Sodium phosphate, dibasic

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

#### Flammability:

**Autoignition Temperature (Solid) (°C):** No data available

**Flammability (Solids):** No data available

**Flash Point (Liquid) (°C):** No data available

**Upper Explosive Limits (Liquid) (% by Vol.):** No data available

**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable at normal conditions

#### Possibility of Hazardous Reactions

**Oxidizing Properties:** No data available

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.

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

**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

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

**Short Term:** May cause eye irritation. Accidental ingestion may cause effects similar to those seen in clinical use.

**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.

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### 11. TOXICOLOGICAL INFORMATION

#### Acute Toxicity: (Species, Route, End Point, Dose)

##### **Latanoprost**

Rat Oral LD 50 > 50 mg/kg  
Rat Para-periosteal LD 50 > 2mg/kg  
Mouse Oral LD50 > 50mg/kg

##### **Sodium chloride**

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

##### **Benzalkonium chloride**

Rat Oral LD50 240 mg/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 - GPMT 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

#### 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  
2 Year(s) Rat Oral 0.2 mg/kg/day NOAEL None identified

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### **Latanoprost**

Fertility and Embryonic Development Rabbit Intravenous 0.001 mg/kg/day NOAEL Embryotoxicity  
Reproductive & Fertility Rat Intravenous 0.035 mg/kg/day NOAEL Paternal toxicity, Not Teratogenic  
Prenatal & 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

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### 11. TOXICOLOGICAL INFORMATION

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### **Latanoprost**

Bacterial Mutagenicity (Ames) Bacteria Negative  
*In Vitro* Mammalian Cell Mutagenicity Mouse Lymphoma Negative  
*In Vitro* Chromosome 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 IARC, NTP or OSHA.

### 12. ECOLOGICAL INFORMATION

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

**Toxicity:** No data available

**Persistence and Degradability:** No data available

#### **Bio-accumulative Potential:**

##### **Partition Coefficient: (Method, pH, Endpoint, Value)**

##### **Latanoprost**

Predicted 7.4 Log D 3.65

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** 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 wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

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### 15. REGULATORY INFORMATION

#### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

##### Canada - WHMIS: Classifications

##### **WHMIS hazard class:**

None required

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

##### **Latanoprost**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS/ELINCS List	Not Listed

##### **Sodium Phosphate Monobasic, Monohydrate**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

##### **Sodium chloride**

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

##### **Sodium phosphate, dibasic**

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present

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### 15. REGULATORY INFORMATION

Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

#### Water

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

#### Benzalkonium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

**Data Sources:** Publicly available toxicity information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 3 - Composition / Information on Ingredients.

**Revision date:** 31-Mar-2016  
Product Stewardship Hazard Communication

**Prepared by:** Global Environment, Health, and Safety Operations

It is believed that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time

**End of Safety Data Sheet**