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

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

No data available

Note: 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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Latanoprost</td>
<td>130209-82-4</td>
<td>Not Listed</td>
<td>Repr. 2 (H361d)</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td></td>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Phosphate Monobasic, Monohydrate</td>
<td>10049-21-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
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
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/m³

Sodium chloride
Latvia OEL - TWA 5 mg/m³
Lithuania OEL - TWA 5 mg/m³

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
Odor: No data available.
Molecular Formula: Mixture

Solvent Solubility: No data available

Color: Colorless to light yellow
Odor Threshold: No data available.
Molecular Weight: Mixture
### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
<td>Latanoprost Predicted 7.4 Log D 3.65</td>
</tr>
<tr>
<td>Decomposition Temperature (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.)</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 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.
11. TOXICOLOGICAL INFORMATION

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latanoprost</td>
<td>Oral</td>
<td>LD50</td>
<td>&gt; 50 mg/kg</td>
</tr>
<tr>
<td>Latanoprost</td>
<td>Para-periosteal</td>
<td>LD50</td>
<td>&gt; 2mg/kg</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Oral</td>
<td>LD50</td>
<td>3000 mg/kg</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Oral</td>
<td>LD50</td>
<td>4000 mg/kg</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>Oral</td>
<td>LD50</td>
<td>240 mg/kg</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Material</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latanoprost</td>
<td>Rabbit</td>
<td>Slight</td>
<td></td>
</tr>
<tr>
<td>Latanoprost</td>
<td>Rabbit</td>
<td>No effect</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Rabbit</td>
<td>Mild</td>
<td></td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>Guinea Pig</td>
<td>Negative</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Rabbit</td>
<td>Moderate</td>
<td></td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>Guinea Pig</td>
<td>Negative</td>
<td></td>
</tr>
</tbody>
</table>

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

<table>
<thead>
<tr>
<th>Material</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latanoprost</td>
<td>Oral</td>
<td>0.2 mg/kg/day</td>
<td>NOAEL None identified</td>
</tr>
<tr>
<td>Latanoprost</td>
<td>Oral</td>
<td>0.2 mg/kg/day</td>
<td>NOAEL None identified</td>
</tr>
<tr>
<td>Latanoprost</td>
<td>Oral</td>
<td>0.001 mg/kg/day</td>
<td>NOAEL None identified</td>
</tr>
<tr>
<td>Latanoprost</td>
<td>Oral</td>
<td>0.2 mg/kg/day</td>
<td>NOAEL None identified</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latanoprost</td>
<td>Rabbit</td>
<td>Intravenous 0.001 mg/kg/day</td>
<td>NOAEL Embryotoxicity</td>
</tr>
<tr>
<td>Latanoprost</td>
<td>Rat</td>
<td>Intravenous 0.035 mg/kg/day</td>
<td>NOAEL Paternal toxicity, Not Teratogenic</td>
</tr>
<tr>
<td>Prenatal &amp; Postnatal Development</td>
<td>Rat</td>
<td>Intravenous 0.01 mg/kg/day</td>
<td>NOAEL No effects at maximum dose</td>
</tr>
<tr>
<td>Embryo / Fetal Development</td>
<td>Rat</td>
<td>Intravenous 0.05 mg/kg/day</td>
<td>NOAEL Paternal toxicity, Not Teratogenic</td>
</tr>
</tbody>
</table>
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.
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 5000 lb
and their Reportable Quantities:
2270 kg
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material</th>
<th>Australia (AICS):</th>
<th>EU EINECS/ELINCS List</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Present</td>
<td>231-448-7</td>
</tr>
</tbody>
</table>

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

**Prepared by:** Product Stewardship Hazard Communication

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