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

Material Name: Latanoprost Ophthalmic Solution (Greenstone LLC)

Trade Name: Not applicable
Synonyms: None
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for glaucoma

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to slightly yellow solution

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

Additional Hazard Information:
- **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.

EU Indication of danger: Not classified


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latanoprost</td>
<td>130209-82-4</td>
<td>Not Listed</td>
<td>Repr.Cat.3;R63</td>
<td>&lt;0.1</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
MATERIAL SAFETY DATA SHEET

Material Name: Latanoprost Ophthalmic Solution (Greenstone LLC)
Revision date: 02-Mar-2011

Sodium Phosphate Monobasic, Monohydrate 10049-21-5 Not Listed Not Listed *
Sodium chloride 7647-14-5 231-598-3 Not Listed *
Water 7732-18-5 231-791-2 Not Listed *
Sodium phosphate, dibasic 7558-79-4 231-448-7 Not Listed *

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

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

4. 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.

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 fire fighting 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

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

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.

Measures for Environmental Protections: Place waste in an appropriately labeled, 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 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Latanoprost
Manufacturer OEL: 0.7ug/m³

Sodium chloride
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.

Personal Protective Equipment:

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

Chemical Stability: Stable at normal conditions
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
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 LD50 > 50 mg/kg
- Rat Para-periosteal LD50 > 2 mg/kg
- Mouse Oral LD50 > 50 mg/kg

Sodium chloride
- Rat Oral LD50 3000 mg/kg
- Mouse Oral LD50 4000 mg/kg

Benzalkonium chloride
- Rat Oral LD50 240 mg/kg

Sodium phosphate, dibasic
- Rat Oral LD50 17 g/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

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
- 2 Year(s) Rat Oral 0.2 mg/kg/day NOAEL None identified
11. TOXICOLOGICAL INFORMATION

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

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.

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

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 the MSDS contains all of the information required by the 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 for Drugs and Poisons: Schedule 5

Sodium chloride
Inventory - United States TSCA - Sect. 8(b): Listed
Australia (AICS): Listed
EU EINECS/ELINCS List: 231-598-3

Water
Inventory - United States TSCA - Sect. 8(b): Listed
Australia (AICS): Listed
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List: 231-791-2

Sodium phosphate, dibasic
CERCLA/SARA Hazardous Substances and their Reportable Quantities: 2270 kg final RQ 5000 lb final RQ
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Inventory - United States TSCA - Sect. 8(b)</th>
<th>Listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia (AICS):</td>
<td>Listed</td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>231-448-7</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Full text of S3 R phrases

R63 - Possible risk of harm to the unborn child.

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Prepared by: Product Stewardship Hazard Communications
             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