



SAFETY DATA SHEET

Revision date: 07-Oct-2015

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE 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

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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

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

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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. |

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

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7. HANDLING AND STORAGE

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.

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 |
| 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

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9. PHYSICAL AND CHEMICAL PROPERTIES

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.

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

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11. TOXICOLOGICAL INFORMATION

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 NOEL None identified
13 Week(s) Rat Oral 0.2 mg/kg/day NOEL None identified
13 Week(s) Dog Intravenous 0.001 mg/kg/day NOEL None identified
2 Year(s) Rat Oral 0.2 mg/kg/day NOEL 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 NOEL Embryotoxicity
Reproductive & Fertility Rat Intravenous 0.035 mg/kg/day NOEL Paternal toxicity, Not Teratogenic
Prenatal & Postnatal Development Rat Intravenous 0.01 mg/kg/day NOEL No effects at maximum dose
Embryo / Fetal Development Rat Intravenous 0.05 mg/kg/day NOEL 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 NOEL Not carcinogenic
2 Year(s) Rat Oral 0.2 mg/kg/day NOEL Not carcinogenic

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11. TOXICOLOGICAL INFORMATION

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

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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 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 16 - Other Information.

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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