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

Product Identifier

Material Name: Latanoprost Solution

Trade Name: Xalatan; Xal-Ease; Hysite

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

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

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Latanoprost</td>
<td>130209-82-4</td>
<td>Not Listed</td>
<td>Repr. 2 (H361d)</td>
<td>&lt;0.1</td>
</tr>
</tbody>
</table>
3. COMPOSITION / INFORMATION ON INGREDIENTS

<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 phosphate, dibasic</td>
<td>7558-79-4</td>
<td>231-448-7</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</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>

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 CLP/GHS abbreviations 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 firefighting 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. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. 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
Pfizer OEL TWA-8 Hr: 0.7µg/m³

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

Benzalkonium chloride
Pfizer Occupational Exposure Band (OEB): OEB 2 - Sensitizer (control exposure to the range of 100ug/m³ to < 1000ug/m³, provide additional precautions to protect from skin contact)

Sodium phosphate, dibasic
Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Sodium chloride
Pfizer Occupational Exposure Band (OEB): OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Exposure Controls
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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. It is recommended that all operations be fully enclosed and no air recirculated.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
<th>Color:</th>
<th>Colorless to light yellow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available.</td>
<td>Odor Threshold:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

| 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 |
| 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
SAFETY DATA SHEET

Material Name: Latanoprost Solution
Revision date: 02-Apr-2019

10. STABILITY AND REACTIVITY

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

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: 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. Not expected to cause skin 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 LD50 > 50 mg/kg
- Rat Para-periosteal LD50 > 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

LATANOPROST SOLUTION
11. TOXICOLOGICAL INFORMATION

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

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

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
15. REGULATORY INFORMATION

Benzalkonium 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: 231-791-2

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
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: 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

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

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:
- Pfizer proprietary drug development information.
- 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 11 - Toxicology Information.
- Updated Section 7 - Handling and Storage.
- Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 02-Apr-2019
Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations
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End of Safety Data Sheet