



SAFETY DATA SHEET

BIMATOPROST OPHTHALMIC SOLUTION (0.03%)

1. Product and Company Information

Product Identifier: Bimatoprost Ophthalmic Solution (0.03%)
Synonyms: None
National Drug Code: 70069- 401-01 (2.5 mL),
70069- 402-01 (5 mL)
70069- 403-01 (7.5 mL)
Recommended Use: Pharmaceutical Eye drops
Company: Somerset Therapeutics LLC
Somerset, NJ 08873
Contact Telephone: 1800-417-9175
E-Mail:
Emergency Phone Number:

2. Hazardous(s) Identification

Physical Hazards: Not classifiable
Health Hazards: Not classifiable.
Symbol(s): None.
Signal Word: None.
Hazard Statement(s): None.
Precautionary Statement(s): None.
Hazards Not Otherwise Classified: None
Supplementary Information: Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System

3. Composition and Information on Ingredients

Chemical Name	CAS Number
Bimatoprost	155206-00-1
Benzalkonium Chloride NF	8001-54-5
Citric acid Monohydrate USP	77-92-9
Sodium Chloride USP	7647-14-5
Dibasic sodium phosphate USP	7558-79-4
Sodium Hydroxide NF	1310-73-2
Hydrochloric Acid NF	7647-01-0
Water for Injection USP	7732-18-5

The exact percentage (concentration) of the composition is being withheld as a trade secret is required.

4. First Aid Measures

- Eye Contact** Flush eyes with plenty of water. Get medical attention.
- Skin Contact:** Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
- Inhalation:** Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
- Ingestion:** If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.

5. Fire-Fighting Measures

- Extinguishing Media:** Water spray, carbon dioxide, dry chemical powder or appropriate foam.
- Hazardous Combustion Products:** Hazardous combustion or decomposition products are expected when the product is exposed to fire.
- Fire Fighting Procedures:** For single units (packages): No special requirements needed.
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
- Fire / Explosion Hazards:** Assume that this product is capable of sustaining combustion.

6. Accidental Release Measures

- Health and Safety Precautions:** Wear protective clothing and equipment consistent with the degree of hazard.
- Measures for Cleaning / Collecting:** Collect and place it in a suitable, properly labeled container for recovery or disposal.
- Measures for Environmental Protections:** For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

7. Handling and Storage:

- Handling:** No special control measures required for the normal handling of this product.
- Storage:** Store the product 2 to 25°C (36 to 77°F).

8. Exposure Controls / Personal Protection

Exposure Limits Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling..

Hands: Not Available

Eyes: Not Available

Respiratory protection: Not Available

9. Physical and Chemical Properties

Appearance : Clear colorless solution

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapour Pressure (kPa): No data available

Vapour Density (g/ml): No data available

Specific Gravity: 0.9000 to 1.1000 g/mL

Viscosity: No data available

Flammability: Not flammable

Flash Point (Liquid) (°C): Not flammable

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 under recommended storage conditions

Incompatible Materials: No data available

Hazardous Decomposition Products No data available

Hazardous Polymerization No data available

11. Toxicological Information

Bimatoprost was not carcinogenic in either mice or rats when administered by oral gavage at doses of upto 2 mg/kg/day and 1 mg/kg/day respectively (at least 192 and 291 times the recommended human exposure based on blood AUC levels respectively) for 104 weeks. Bimatoprost was not mutagenic or clastogenic in the Ames test, in the mouse lymphoma test, or in the *in vivo* mouse micronucleus tests. Bimatoprost did not impair fertility in male or female rats upto doses of 0.6 mg/kg/day (at least 103 times the recommended human exposure based on blood AUC levels).

12. Ecological Information

No relevant studies identified.

13. Disposal Conditions

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

14. Transportation Information

IATA/ICAO - Not Regulated
IATA Proper shipping Name : N/A
IATA UN/ID No : N/A
IATA Hazard Class : N/A
IATA Packaging Group : N/A
IATA Label : N/A
IMDG - Not Regulated
IMDG Proper shipping Name : N/A
IMDG UN/ID No : N/A
IMDG Hazard Class : N/A
IMDG Flash Point : N/A
IMDG Label : N/A
DOT - Not Regulated
DOT Proper shipping Name : N/A
DOT UN/ID No : N/A
DOT Hazard Class : N/A
DOT Flash Point : N/A
DOT Packing Group : N/A
DOT Label : N

15. Regulatory Information

DOT Designations: Non-hazardous
RCRA Hazardous Waste: Not Listed
FDA Designations: Prescription only medication.
NDC No. 70069- 401-01 (2.5 mL),
70069- 402-01 (5 mL)
70069- 403-01 (7.5 mL)

16. Other Information

NFPA Rating:
Health: 1
Flammability: 0
Reactivity: 0

Revision Date: 08/10/2019
Revision Number: 01

Disclaimer: As of the date of issuance, we are providing available information relevant to the handling of this material. All information contained herein is offered with the good faith belief that it is accurate. In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.