

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

**Material** **Bimatoprost Ophthalmic Solution, 0.03%**

**Manufacturer** Lupin Limited  
Pithampur (M.P.) - 454 775  
INDIA.

**Distributor** Lupin Pharmaceuticals, Inc.  
Harborplace Tower, 21<sup>st</sup> Floor  
111, South Calvert Street  
Baltimore, MD 21202  
United States

Tel. 001-410-576-2000

Fax 001-410-576-2221

### Section 2: Hazard(s) Identification

#### Section 2, Hazard(s) identification

**Fire and Explosion** Expected to be non-combustible.

**Health** None

**Environment** No information is available about the potential of this product to produce adverse environmental effects.

### Section 3: Composition/Information on Ingredients

#### Section 3, Composition/information on ingredients

<b>Ingredients</b>	<b>CAS</b>
Bimatoprost	155206-00-1

## Section 4: First-Aid Measures

### Section 4, First-aid measures

<b>Ingestion</b>	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.
<b>Inhalation</b>	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Flush eyes with plenty of water. Get medical attention.

### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
--------------------------	---

<b>OVERDOSAGE</b>	<p>No information is available on overdosage in humans. If overdose with bimatoprost ophthalmic solution, 0.03% occurs, treatment should be symptomatic.</p> <p>In oral (by gavage) mouse and rat studies, doses up to 100 mg/kg/day did not produce any toxicity. This dose expressed as mg/m<sup>2</sup> is at least 70 times higher than the accidental dose of one bottle of bimatoprost ophthalmic solution, 0.03% for a 10 kg child.</p>
-------------------	--

## Section 5: Fire-Fighting Measures

### Section 5, Fire-fighting measures

<b>Fire and Explosion Hazards</b>	Assume that this product is capable of sustaining combustion.
<b>Extinguishing Media</b>	Water spray, carbon dioxide, dry chemical powder or appropriate foam.

**Special Firefighting 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.

**Hazardous Combustion Products**

Hazardous combustion or decomposition products are expected when the product is exposed to fire.

**Section 6: Accidental Release Measures****Section 6, Accidental release measures****Personal Precautions**

Wear protective clothing and equipment consistent with the degree of hazard.

**Environmental Precautions**

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

**Clean-up Methods**

Collect and place it in a suitable, properly labeled container for recovery or disposal.

**Section 7: Handling and Storage****Section 7, Handling and storage****Handling**

No special control measures required for the normal handling of this product.

**Storage**

Bimatoprost ophthalmic solution, 0.03% should be stored at 2 to 25°C (36 to 77°F).

**Section 8: Exposure Controls/Personal Protection****Section 8, Exposure controls/personal protection**

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

## Section 9: Physical and Chemical Properties

### Section 9, Physical and chemical properties

#### Physical Form

Bimatoprost ophthalmic solution, 0.03% is supplied sterile in opaque white low density polyethylene bottle which is closed with white low density polyethylene nozzle and then with turquoise colored high density polyethylene cap in the following sizes:

2.5 mL fill in a 5 mL container	-	NDC 68180-429-01
5 mL fill in a 10 mL container	-	NDC 68180-429-02
7.5 mL fill in a 10 mL container	-	NDC 68180-429-03

## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

### Section 11, Toxicological information

#### CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

Bimatoprost was not carcinogenic in either mice or rats when administered by oral gavage at doses of up to 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 up to doses of 0.6 mg/kg/day (at least 103 times the recommended human exposure based on blood AUC levels).

## Section 12: Ecological Information\* (non-mandatory)

No relevant studies identified.

## Section 13: Disposal Considerations\* (non-mandatory)

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

## Section 14: Transport Information\* (non-mandatory)

### 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/A

## Section 15: Regulatory Information\* (non-mandatory)

This Section Contains Information relevant to compliance with other Federal and/or state laws.

## Section 16: Other Information

### **Section 16, Other information**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**Lupin** shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this MSDS.