LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	**Bromfenac Ophthalmic Solution 0.07%**
Manufacturer	**Lupin Limited** Pithampur (M.P.) – 454 775 INDIA.
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221
Use of the Substance/mixture	Pharmaceuticals

Section 2: Hazard(s) Identification

Fire and Explosion	Expected to be non-combustible.
Health	May cause eye irritation in sensitive individuals May cause skin irritation or dryness. May be harmful if swallowed.
Environment	No information is available about the potential of this product to produce adverse environmental effects. Avoid release to the environment.

Section 3: Composition/Information on Ingredients

Composition/information on ingredient:

Ingredients	CAS No.	Ingredients	CAS No.
Bromfenac Sodium	91714-93-1	Sodium Borate NF	13840-56-7
Benzalkonium Chloride Solution 50% NF	8001-54-5	Boric Acid NF	10043-35-3
Edetate Disodium USP (Dihydrate)	139-33-3	Sodium Sulfite NF	7757-83-7
Tyloxapol	25301-02-4	Sodium Hydroxide NF	1310-73-2
Povidone USP	9003-39-8	Nitrogen NF (gas)	7727-37-9

* The exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: First-Aid Measures

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.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs If not breathing, provide artificial respiration assistance.
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.
Eye Contact	Flush eyes with plenty of water. Get medical attention.
NOTES TO HEALTH PROFESSIONALS	
Medical Treatment	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.

Section 5: Fire-Fighting Measures

Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	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

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

Handling	Avoid contact with the product and use caution to prevent puncturing containers. Normal room ventilation is expected to be adequate for routine handling of this product.
Storage	Store at 20– 25°C (68-77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Keep this and all medications out of reach of children.

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

Physical Form	**How Supplied** A sterile, topical, nonsteroidal anti-inflammatory drug (NSAID) for ophthalmic use supplied in a white low density polyethylene bottle fitted with a white low density polyethylene nozzle and sealed with grey colored high density polyethylene cap with tamper-evident ring.

Section 10: Stability and Reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term carcinogenicity studies in rats and mice given oral doses of bromfenac up to 0.6 mg/kg/day (900 times the recommended human ophthalmic dose [RHOD] of 1.67 mcg/kg in 60 kg person on a mg/kg/basis, assuming 100% absorbed) and 5 mg/kg/day (7500 times RHOD), respectively revealed no significant increases in tumor incidence.

Bromfenac did not show mutagenic potential in various mutagenicity studies, including the reverse mutation, chromosomal aberration, and micronucleus tests.

Bromfenac did not impair fertility when administered orally to male and female rats at doses up to 0.9 mg/kg/day and 0.3 mg/kg/day, respectively (1300 and 450 times RHOD, respectively).

Section 12: Ecological Information

No relevant studies identified.

Section 13: Disposal Considerations

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

Section 14: Transport 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/A

Section 15: Regulatory Information

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

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 SDS.