

SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS),
Sixth Revised Edition UNITED NATIONS
New York and Geneva, 2023

Bimatoprost Ophthalmic Solution USP, 0.01%

1. IDENTIFICATION

GHS Product identifier: Bimatoprost Ophthalmic Solution USP, 0.01%

Product code: #

Chemical Description: (Z)-7-[(1R,2R,3R,5S)-3,5-dihydroxy-2-[(E,3S)-3-hydroxy-5-phenylpent-1-enyl]cyclopentyl]-N-ethylhept-5-enamide

Other means of identification:

Recommended use of the chemical: Bimatoprost Ophthalmic solution is a first-line treatment for reducing high pressure inside the eye caused by open-angle glaucoma and ocular hypertension.

Restrictions on use: The product should be used only for the above mentioned uses and may not be used for any other purpose than stated above.

Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Manufactured by:

Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification

Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route
Reproductive toxicity	1B	-

Labeling

Globally Harmonized System, UN (GHS)



Classification	
Signal Word	Danger
Hazard Statements:	H360: May damage fertility or unborn child
Precautionary Statements:	P301+P312 If swallowed: Call a poison center/doctor if you feel unwell P264 Wash thoroughly after handling P272 Contaminated work clothing must not be allowed out of the workplace. P273: Avoid release to the environment P391:Collect spillage

Other hazards which do not result in classification: none

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous ingredients	CAS	Content (mg/ml)
Bimatoprost	155206-00-1	0.05 – 0.15
Boric Acid	10043-35-3	7.1 – 9.1
Sodium Borate	1303-96-4	3.95 – 5.95
Glycerin	56-81-5	8.9 – 10.9
Benzalkonium chloride	68424-85-1	0.1 – 0.3
Sodium hydroxide	1310-73-2	q.s. to pH
Hydrochloric acid	7647-01-0	q.s. to pH
Water for Injection	7732-18-5	q.s.

4. FIRST-AID MEASURES

Inhalation

Not relevant to this mixture.

Skin contact

If skin irritation occurs, seek medical attention.

Eye contact

If adverse reactions occur, contact your physician.

Ingestion

Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if patient exhibits adverse effects.

Advice for the doctor

Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Dry Chemical Foam, Carbon dioxide, Water spray or alcohol-resistant foam.

Fire/explosion hazard

None known. Expected to be non-combustible.

Specific hazards arising from the mixture

No data available.

Personal protection

Self-contained breathing apparatus.

Special exposure hazards

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

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions

Be careful not to let it flow into rivers, etc., since adverse effects on the environment are concerned.

Spillage procedure

Clean up any spills as soon as possible.

7. HANDLING AND STORAGE

Handling

Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Fire precautions

Avoid ignition sources.

Keep away from heat/sparks/open flames/hot surfaces.

Storage facilities

Store the product in original container with the cap tightly closed at a controlled room temperature of 2-25°C (36-77°F), to maintain product integrity. Use before expiration date marked on carton and/or container. Protect from light.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Components with occupational exposure limits

This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Bimatoprost Powder: ACGIH TLV - 10 mg/m³ (inhalable) and 3 mg/m³ (respirable).

Borax: OSHA (PEL): 1 mg/m³ (8-hour Time-Weighted Average - TWA).

Boric acid: ACGIH TLV - 2 mg/m³ for an 8-hour TWA (inhalable fraction) and 6 mg/m³ for a 15-minute Short-Term Exposure Limit (STEL)

Occupational exposure controls

Appropriate engineering controls

Good general ventilation should be used. Ventilation rates should be matched to conditions.

If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Respiratory protection

No respiratory protection is required during normal handling.

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place.

Hand protection

Gloves are not required under normal handling conditions.

Eye protection

Avoid contact with the eye. No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear

Form: Aqueous solution

Colour: Colourless

Odour: Not tested

pH: 6.8-7.8

Boiling point: 100°C (212°F)

Specific gravity: Not tested

Vapor Density: >1

Solubility: Soluble in water

n-Octanol/Water Partition Coefficient: Not tested

10. STABILITY AND REACTIVITY

Conditions to avoid

Stable under recommended storage conditions. Avoid extreme heat or cold. Do not freeze.

Incompatible Materials: Oxidising agents

Hazardous decomposition products

Toxic fumes when heated to decomposition.

11. TOXICOLOGICAL INFORMATION

Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Acute toxicity – Bimatoprost compound – Acute toxicity - 4

UN GHS • Classification criteria not met

Primary Irritation (Skin/eyes) – Substance classified as category 2 for eye irritation.

Bimatoprost is <1% in the mixture and hence not classified.

Respiratory or Skin sensitization – Substances not classified

Carcinogenicity - UN GHS • Classification criteria not met

Reproductive toxicity –

Bimatoprost –Repro. 1B.

Boric acid - Repr. 1B

Borax- Repr. 1B

Repro. 1B drug is a presumed reproductive toxicant based on evidence from experimental animals. Mixture is therefore classified as Repro. 1B

Specific target organ toxicity single exposure - UN GHS • Classification criteria not met

Specific target repeated exposure - UN GHS • Classification criteria not met.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Data not available.

Persistence and degradability:

Data not available.

Bio accumulative potential:

Data not available

Mobility in soil - Not tested

Classification is not possible.

Additional information

Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal

Observe specific national regulation.

Contaminated packaging

Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

Not considered dangerous for transport

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2003 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2019

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

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