SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Ninth Revised Edition UNITED NATIONS New York and Geneva, 2021

Moxifloxacin Hydrochloride Ophthalmic Solution USP 0.5%

1. IDENTIFICATION

GHS Product identifier: Moxifloxacin Hydrochloride Ophthalmic Solution USP 0.5%

Product code: #

Chemical Description: 1-Cyclopropyl-6-fluoro-1,4-dihydro-8-methoxy-7-[(4a*S*,7a*S*)-octahydro-1*H*-pyrrolo[3,4-*b*]pyridin-6-yl]-4-oxo-3-quinolinecarboxylic Acid Monohydrochloride

Other means of identification:

Recommended use of the chemical: Moxifloxacin eye solution is used to treat infections of the eye, including bacterial conjunctivitis.

Restrictions on use: The product is for topical ophthalmic use only. Not for injection.
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)

None

Labeling

Globally Harmonized System, UN (GHS)

None

Classification	
Signal Word	**None**
Hazard Statements:	None
Precautionary Statements:	P273: Avoid release to the environment. P264: Wash hands and face thoroughly after handling. P280-Wear protective gloves, face protection. P305+P351+P338+P310: If in eyes: Rinse cautiously with water for several minutes. P391:Collect spillage

Other hazards which do not result in classification: none

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous ingredients	CAS	Content (%)
Moxifloxacin Hydrochloride Monohydrate	192927-63-2	0.5679 (0.500)@
Boric Acid	10043-35-3	0.3
Sodium Chloride	7647-14-5	0.6600
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. to 1 ml

@-Moxifloxacin Hydrochloride Monohydrate 5.679 mg/ml is equivalent to 5.000 mg/ml of Moxifloxacin.

4. FIRST-AID MEASURES

Inhalation

No specific treatment is necessary since this mixture is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin contact

No specific treatment is necessary since this mixture is not likely to be hazardous by contact with the skin or mucous membranes.

Eye contact

If large amounts enter into the eye, rinse immediately with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do – continue rinsing. Seek medical attention**.**

Ingestion

Rinse mouth and then drink plenty of water.
If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately.

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

Carbon monoxide, nitrogen oxides, hydrogen chloride, hydrogen fluoride.

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 2-25ºC (36-77ºF), 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

CAS No	Name	ACGIH	NIOSH	OSHA
7647-01-0	Hydrochloric acid	2 ppm Ceiling	5 ppm Ceiling; 7 mg/m^3 Ceiling	5 ppm Ceiling; 7 mg/m^3 Ceiling

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
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used.

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: Slightly yellow to greenish yellow
Odour: Not known
pH: 6.3-7.9
Density: Data not available
Specific Gravity: Data not available
Viscosity: Data not available

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.

Materials to avoid

None

Incompatible Materials: Oxidising agents

Hazardous decomposition products
Carbon dioxide, Carbon monoxide, Nitrogen oxides (NOx), Hydrogen fluoride, Hydrogen chloride

11. TOXICOLOGICAL INFORMATION.

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

Acute toxicity – Not classifiable

Primary Irritation (Skin/eyes) - Data not available

Respiratory or Skin sensitization - Data not available

Carcinogenicity, mutagenesis, fertility-

Moxifloxacin had no effect on fertility in male and female rats at oral doses as high as 500 mg/kg/day, approximately 21,700 times the highest recommended total daily human ophthalmic dose. At 500 mg/kg orally there were slight effects on sperm morphology (head-tail separation) in male rats and on the estrous cycle in female rats.

Although active ingredient is classified for germ cell mutagenicity as category 2, mixture is not classifiable since it has <1% of the active ingredient.

Reproductive toxicity – Not classified

Specific target organ toxicity single exposure - Data not available

Specific target repeated exposure - Data not available

12. ECOLOGICAL INFORMATION

Product administered to patients present a negligible impact on the environment.

Ecotoxicity
GHS Classification for mixture is not possible due to lack of data.

Persistence and degradability:
Not tested

Bio accumulative potential;
Not tested

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 2009

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.

MSDS Changes
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