

SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS),
Sixth Revised Edition UNITED NATIONS
New York and Geneva, 2015

Ofloxacin Otic Solution, 0.3% w/v

1. IDENTIFICATION

GHS Product identifier: Ofloxacin Otic Solution, 0.3% w/v

Product code: #

Chemical Description: "9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de] [1,4]benzoxazine-6-carboxylic acid"

Other means of identification:

Recommended use of the chemical:

Ofloxacin Otic Solution is indicated for the treatment of infections such as otitis externa, chronic suppurative otitis media and acute otitis media caused by susceptible bacteria

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)

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
Ofloxacin	82419-36-1	0.3%
Benzalkonium chloride equivalent to Benzalkonium chloride (50% solution)	8001-54-5	0.0025% (0.005% @)
Sodium chloride	7647-14-5	0.9%
Hydrochloric acid	7647-01-0	q.s to adjust pH
Sodium Hydroxide	1310-73-2	q.s to adjust pH

@-Label claim of Benzalkonium chloride solution 100% is 0.0025%. Hence, 0.005% is mentioned for benzalkonium chloride 50% solution

4. FIRST-AID MEASURES

Inhalation

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

Eye contact

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.

Most important symptoms and effects, both acute and delayed

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving systemic quinolones, including ofloxacin. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria, and itching. If an allergic reaction to ofloxacin occurs, discontinue the drug. Oxygen and airway management, including intubation should be administered as clinically indicated.

Advice for the doctor

Additional details are available on the product package insert or the Physicians Desk Reference

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

Keep tightly closed. Store at room temperature 20 – 25 °C (68 – 77 °F) to maintain product integrity. Use before expiration date marked on carton/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. If exposure limits have not been established, maintain airborne levels to an acceptable level.

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 required during normal handling.

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: Pale light yellow to yellow

Odour: Odourless

pH: 6.0 -7.0

Density: 0.95 to 1.05 g/mL

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: None.

Hazardous decomposition products

None

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity - UN GHS • Classification criteria not met

Ofloxacin LD₅₀=5450 mg/kg (oral in mice)

Primary Irritation (Skin/eyes) - UN GHS • Classification criteria not met

Respiratory or Skin sensitization - UN GHS • Classification criteria not met

Carcinogenicity - UN GHS • Classification criteria not met

Reproductive toxicity - UN GHS • Classification criteria not met

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

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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