

SAFETY DATA SHEET

Tobramycin Inhalation Solution USP, 300 mg/5 mL

1. IDENTIFICATION

Product identifier: Tobramycin Inhalation Solution USP

Product code: #

Chemical Description: 0-3-amino-3-deoxy- α -D-glucopyranosyl- (1 \rightarrow 4)-0-[2,6-diamino-2,3,6-trideoxy- α -D-ribohexopyranosyl-(1 \rightarrow 6)]-2-deoxy-L-streptamine. C₁₈H₃₇N₅O₉

Other means of identification: --

Recommended use of the chemical: Used in the management of cystic fibrosis patients with Pseudomonas aeruginosa.

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.

Manufactured by:

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

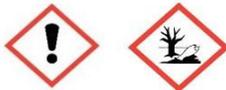
Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification

Classification	Category	Exposure Route
Eye irritation	2B	-
Skin Irritation	2	Dermal
Skin sensitization	1	-
STOT SE	3	-
Aquatic toxicity	1	-

Labelling



Classification	
Signal Word	Warning
Hazard Statements:	H316: Causes skin irritation H317: May cause an allergic skin reaction H320: Causes eye irritation H335: May cause respiratory irritation H400: Very toxic to aquatic life

Precautionary Statements:	<p>P273: Avoid release to the environment. P264: Wash hands and face thoroughly after handling. P280-Wear protective gloves, face protection. P302+P352+P332+P313+P362+P364: If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice or attention. Take off contaminated clothing and wash it before reuse. P304+P340: IF INHALED Remove person to fresh air and keep comfortable for breathing. P305+P351+P338+P310: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison centre or doctor. P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER /doctor</p> <p>P391:Collect spillage</p> <p>Other hazards which do not result in classification: none</p>
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3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous ingredients	CAS	Content
Tobramycin	32986-56-4	7.5%
Sodium chloride	7647-14-5	<1%
Sodium Hydroxide	7647-01-0	q.s to adjust pH
Sulphuric acid 95-98%	1310-73-2	q.s to adjust pH
Water for injection	7732-18-5	q.s

4. FIRST-AID MEASURES

Inhalation

In case of irritation of the respiratory system or mucous membranes, seek medical attention. Move to fresh air. If not breathing, give artificial respiration. Seek medical attention in case of prolonged exposure.

Skin contact

Wash affected skin with soap and plenty of ice water. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. If skin irritation or dermatitis commences or persists, seek medical attention.

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. Seek medical attention.

Advice for the doctor

Tobramycin is not significantly absorbed following oral administration. Tobramycin serum concentrations may be helpful in monitoring over dosage.



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

Avoid breathing vapour or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases.

Fire precautions

Avoid ignition sources.
Keep away from heat/sparks/open flames/hot surfaces.

Storage facilities

Store as directed by product packaging.
Tobramycin inhalation solution, USP ampules should not be exposed to intense light. The solution in the ampule is slightly yellow, but may darken with age if not stored in the refrigerator; however, the color change does not indicate any change in the quality of the product as long as it is stored within the recommended storage conditions.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values

Sodium Chloride - TWA - 5 mg/m³

Appropriate engineering controls

Medical supervision of all employees who handle or come in contact with respiratory sensitizers is recommended. Handle in accordance with good industrial hygiene and safety practices. Wash hands before breaks and at the end of the workday.

Respiratory protection

Whenever excessive air contamination (dust, mist, vapour) is generated, respiratory protection, with appropriate protection factors should be used to minimize exposure.

Hand protection

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations

Eye protection

Safety glasses. A face shield, if the situation requires

Skin and body protection

Protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear

Form: Aqueous solution

Colour: Colourless or slight yellow to Pale yellow
colour **Odour:** Odourless **pH:** 4.5- 6

Melting point: Not applicable

Solubility: Soluble in water.

Wt/ml – 1.0 to 1.15 gm/mL **n-Octanol/Water**

Partition Coefficient: Not tested

Viscosity, kinematic: Not tested

10. STABILITY AND REACTIVITY

Conditions to avoid

Stable under recommended storage conditions.

Materials to avoid

None

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous decomposition products

Carbon monoxide, carbon dioxide, nitrogen oxides

11. TOXICOLOGICAL INFORMATION

Acute toxicity

LD50 (Rat) Oral - 7500 mg/kg

Acute Toxicity - Dermal: No data available.

Acute Toxicity - Inhalation: No data available.

Primary Irritation

Substance is classified in category 2 for Skin Irritation.

Substance is classified in category 2B for Eye Irritation.

Respiratory or Skin sensitization

Respiratory sensitization category 1

CMR consideration:

Carcinogenicity

Data not available.

Reproductive toxicity

Data not available.

Specific target organ toxicity single exposure:

Category 3

Specific target repeated exposure:

Data not available.



12. ECOLOGICAL INFORMATION

Daphnia magna NOEC 0.36 mg/l (21 days)
Fathead minnow EC₅₀ 10 mg/l (33 days)
Anabeana flos-aquae EC₅₀ 0.051 mg/l (96 Hours)

Mixture is classified as Acute 1. Mixture is also classified as Acute 1 based on the criteria for classification of mixture.

Mixture is not classifiable for chronic aquatic toxicity.

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

UN Number:	Not applicable.
UN Proper Shipping Name:	Not applicable.
Transport Hazard Class (es):	Not applicable.
Packing Group:	Not applicable.
Department of Transportation:	Not regulated as a hazardous material.
International Air Transport Association (IATA):	Not regulated as a dangerous good.
International Maritime Dangerous Good (IMDG):	Not regulated as a dangerous good.



**15. REGULATORY INFORMATION
CLASSIFICATION AND LABELLING**

US Federal Regulations:

**Toxic Substance Control Act
(TSCA):**

This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

**CERCLA Hazardous Substance and Reportable
Quantity:**

Not listed.

SARA 313:

Not listed.

SARA 302:

Not listed.

State Regulations

Massachusetts:

Not listed.

New Jersey:

Tobramycin.

Pennsylvania:

Tobramycin.

California Proposition 65:

Not listed.

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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