Lupin Atlantis Holdings SA

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	**Tobramycin Inhalation Solution, USP** **300 mg/5 mL**
Manufacturer	Catalent Pharma Solutions, LLC Woodstock IL 60098, United States
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

Section 2: Hazard(s) Identification

Section 2, Hazard(s) identification

Fire and Explosion	Expected to be non-combustible.
Health	Tobramycin inhalation solution is contraindicated in patients with a known hypersensitivity to any aminoglycoside.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	**CAS**
Tobramycin	32986-56-4

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
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
OVERDOSAGE	Signs and symptoms of acute toxicity from overdosage of intravenous (IV) tobramycin might include dizziness, tinnitus, vertigo, loss of high-tone hearing acuity, respiratory failure, neuromuscular blockade, and renal impairment. Administration by inhalation results in low systemic bioavailability of tobramycin. Tobramycin is not significantly absorbed following oral administration. Tobramycin serum concentrations may be helpful in monitoring overdosage. In all cases of suspected overdosage, physicians should contact the Regional Poison Control Center for information about effective treatment. In the case of any overdosage, the possibility of drug interactions with alterations in drug disposition should be considered.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Strong dust explosion characteristic. High sensitivity of a dust cloud to ignition, based on minimum ignition energy.
Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Special Firefighting Procedures	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Hazardous Combustion Products	Formation of toxic gases is possible during heating or fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures

Personal Precautions	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Clean-up Methods	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Avoid use of a filtered vacuum to clean spills of dry solids, due to the potential for electrostatic discharge and the strong dust explosion characteristic and high sensitivity to ignition.

Section 7: Handling and Storage

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Handling	Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
Storage	Tobramycin inhalation solution, USP should be stored under refrigeration at 2 to 8ºC/36 to 46ºF. Upon removal from the refrigerator, or if refrigeration is unavailable, Tobramycin inhalation solution, USP pouches (opened or unopened) may be stored at room temperature (up to 25ºC/77ºF) for up to 28 days. Tobramycin inhalation solution, USP should not be used beyond the expiration date stamped on the ampule when stored under refrigeration (2 to 8ºC/36 to 46ºF) or beyond 28 days when stored at room temperature (25ºC/77ºF). 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.

Section 8: Exposure Controls/Personal Protection

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

Section 9, Physical and chemical properties

Physical Form	Tobramycin inhalation solution, USP 300 mg is available as follows: NDC 68180-962-56 5 mL single-dose ampule packed in cartons of 56 ampules (14 pouches, each containing 4 ampules).

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

A two-year rat inhalation toxicology study to assess carcinogenic potential of tobramycin inhalation solution has been completed. Rats were exposed to tobramycin inhalation solution for up to 1.5 hours per day for 95 weeks. The clinical formulation of the drug was used for this carcinogenicity study. Serum levels of tobramycin of up to 35 mcg/mL were measured in rats, in contrast to the average 1 mcg/mL levels observed in cystic fibrosis patients in clinical trials. There was no drug-related increase in the incidence of any variety of tumor.

Additionally, tobramycin inhalation solution has been evaluated for genotoxicity in a battery of *in vitro* and *in vivo* tests. The Ames bacterial reversion test, conducted with 5 tester strains, failed to show a significant increase in revertants with or without metabolic activation in all strains. Tobramycin was negative in the mouse lymphoma forward mutation assay, did not induce chromosomal aberrations in Chinese hamster ovary cells, and was negative in the mouse micronucleus test.

Subcutaneous administration of up to 100 mg/kg of tobramycin did not affect mating behavior or cause impairment of fertility in male or female rats.

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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

Section 14: Transport Information

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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

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

Section 16: Other Information

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.