



Tobramycin Sulfate for Injection

Eli Lilly and Company
Material Safety Data Sheet

Effective Date: 04-Jun-2004

Section 1 - Chemical Product and Company

Manufacturer:
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Manufacturer's Emergency Phone:
1-317-276-2000
CHEMTREC:
1-800-424-9300 (North America)
1-703-527-3887 (International)

Common Name: Tobramycin Sulfate for Injection

CAS Number(s): 79645-27-5

Chemical Name: D-Streptamine, O-3-amino-3-deoxy-alpha-D-glucopyranosyl-(1-->6)-O-[2,6-diamino-2,3,6-trideoxy-alpha-D-ribo-hexopyranosyl-(1-->4)]-2-deoxy-, sulfate (2:5) (salt)

Chemical Family: Aminoglycoside antibiotic

Chemical Formula: 2(C₁₈ H₃₇ N₅ O₉) . 5 (H₂ S O₄)

Molecular Weight: 1425.440000

Synonym(s): Tobramycin; Tobramycin Sulfate; Nebramycin Factor 6; 047663 Sulfate; Tobramycine; Sterile Tobramycin Sulfate

Trademarks(s): Distobram; Lilly Tobra; Nebcine; Obracin; Tobracin; Tobra Label; Nebzin; Nebcin In; Tobradistin; Tobramina; Tobragram; Nebcin; Tobra; Gernebcin; Tobrasix; Nebcina

Lilly Serial Number(s): 307274

Lilly Item Code(s): AM7040; DD7125; DD7126; DD7127; DD7128; FS7252; FS7253; VF0182; VF0342; VL0797; VL0798; VL7008; VL7251; VL7602; VP7480

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS
Tobramycin Sulfate for Injection	79645-27-5

Exposure Guidelines:

Tobramycin - LEG 350 micrograms/m³ TWA for 12 hours.

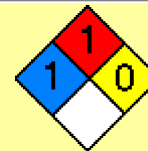
Section 3 - Hazards Identification

Appearance: White to off-white powder

Physical State: Solid

Odor: Odorless

Emergency Overview



Emergency Overview Effective Date: 28-May-1993

Lilly Laboratory Labeling Codes:

Health 1

Fire 1

Reactivity 0

Primary Physical and Health Hazards: Suspect Allergen.

Caution Statement: Tobramycin Sulfate for Injection may cause allergic reactions.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: Based on clinical data for tobramycin, allergic reactions might be expected. The following events have been reported with therapeutic intravenous use of tobramycin: nausea, dermatitis, rash, dizziness, ringing of the ears, hearing loss, kidney effects, blood effects, and changes in serum liver enzyme levels and other clinical chemistry parameters. Aminoglycosides are poorly absorbed from an intact gastrointestinal tract.

Medical Conditions Aggravated by Exposure: Hypersensitivity to aminoglycosides.

Carcinogenicity: No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.

Section 4 - First Aid Measures

Eyes: Flush eyes with plenty of water. Get medical attention.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Notes to Physician:

Tobramycin - In managing overdose, consider the possibility of multiple drug overdoses, interaction among drugs, and unusual drug kinetics in your patient. The initial intervention in a tobramycin overdose is to establish an airway and ensure oxygenation and ventilation. Resuscitative measures

should be initiated promptly if respiratory paralysis occurs. Patients who have received an overdose of tobramycin and who have normal renal function should be adequately hydrated to maintain a urine output of 3 to 5 mL/kg/hr. Fluid balance, creatinine clearance, and tobramycin plasma levels should be carefully monitored until the serum tobramycin level falls below 2 mcg/mL. Patients in whom the elimination half-life is greater than 2 hours or whose renal function is abnormal may require more aggressive therapy. In such patients, hemodialysis may be beneficial.

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found

UEL: No applicable information found

LEL: No applicable information found

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Section 7 - Handling and Storage

Storage Conditions: Controlled Room Temperature: 15 to 30 C (59 to 86 F).

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting:

Respiratory Protection: Use an approved respirator.

Eye Protection: Safety glasses.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face

shield may not be required. Safety glasses are always required.

Section 9 - Physical and Chemical Properties

Appearance: White to off-white powder

Odor: Odorless

Boiling Point: No applicable information found

Melting Point: Decomposes at about 287 C (549 F)

Density: No applicable information found

pH: 9-11 (10% aqueous)

Evaporation Rate: No applicable information found

Water Solubility: Soluble

Vapor Density: No applicable information found

Vapor Pressure: No applicable information found

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

Oral:

Tobramycin sulfate - Rat, 7000 mg/kg, no deaths, reduced activity, diarrhea.

Skin:

Tobramycin sulfate - Rabbit, 500 mg/kg, mortality, diarrhea.

Inhalation:

Tobramycin sulfate - Rat, 6800 mg/m³ for 1 hour, no deaths or toxicity.

Intravenous:

Tobramycin sulfate - Rat, median lethal dose 133 mg/kg, convulsions, reduced activity.
Dog, 100 mg/kg, no deaths, vomiting.

Skin Contact:

Tobramycin sulfate - Rabbit, slight irritant

Eye Contact:

Tobramycin sulfate - Rabbit, slight irritant

Chronic Exposure

Target Organ Effects:

Tobramycin sulfate - Kidney effects (increased blood urea nitrogen, increased creatinine, kidney tissue changes).

Reproduction:

Tobramycin sulfate - No effects identified in animal studies.

Sensitization: No applicable information found.

Mutagenicity:

Tobramycin sulfate - Negative in bacterial cells.

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

TSCA - No

CERCLA - Not on this list
SARA 302 - Not on this list
SARA 313 - Not on this list
OSHA Substance Specific - No

EU Regulations

EC Classification

Not assigned an overall EC classification.

Section 16 - Other Information

MSDS Sections Revised: Sections 2, 3, 4, and 11.

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Eli Lilly and Company
Hazard Communication
317-277-6029

For additional copies contact:

Eli Lilly and Company
1-800-LILLY-Rx (1-800-545-5979)

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN = Chemical Hazard Alert Notice
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association

IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
Kow = Octanol/Water Partition Coefficient
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit
MSDS = Material Safety Data Sheet
MSHA = Mine Safety and Health Administration
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)