



# Tobramycin Sulfate Injection

Effective Date: 04-Jun-2004

Eli Lilly and Company  
Material Safety Data Sheet

## 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 Injection

**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)

**Synonym(s):** 047663 Sulfate Formulation; Tobramycin; Tobramycin Sulfate; Tobramycine; 307274 Formulation

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

**Lilly Item Code(s):** AM0776; AM0780; AM0781; AM0782; AM0783; AM0784; AM0785; AM0797; AM0798; AM0826; AM0828; AM0829; AM0831; AM0832; AM0833; AM0834; AM0835; AM0836; AM0837; AM0838; AM0871; AM7009; AM7010; AM7037; AM7038; AM7039; AM7089; AM7090; AM7092; AM7098; AM7099; AM7129; AM7189; AM7225; AM7342; DD0109; DD0111; DD7187; HY0040; HY0041; HY0042; HY0043; HY0046; HY0055; HY0056; HY7026; HY7027; HY7028; HY7035; HY7036; HY7132; HY7133; HY7488; HY7489; SN5090; UC5341; UC5342; UC8988; UC8989; UC8990; VF0048; VF0171; VF0172; VL0780; VL0781; VL0782; VL7038; VL7040; VL7046; VL7089; VL7090; VL7092; VL7093; VL7186; VL7188; VL7244; VL7293; VL7294; VL7343; VL7344; VL7473; VL7477; VL7480; VL7563; VL7564; VP7473; VP7477

See attached glossary for abbreviations.

## Section 2 - Composition / Information on Ingredients

<b>Ingredient</b>	<b>CAS</b>	<b>Concentration %</b>
Tobramycin Sulfate for Injection	79645-27-5	1 - 8
Phenol	108-95-2	0.125 - 0.5
Sodium Bisulfite	7631-90-5	0.16 - 0.32
Edetate Disodium	139-33-3	0.01
Water for Injection	7732-18-5	90 - 98

**Exposure Guidelines:**

Tobramycin - LEG 350 micrograms/m<sup>3</sup> TWA for 12 hours.

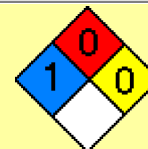
## Section 3 - Hazards Identification

**Appearance:** Clear colorless solution

**Physical State:** Liquid

**Odor:** Odorless

### Emergency Overview



**Emergency Overview Effective Date:** 28-May-1993

**Lilly Laboratory Labeling Codes:**

**Health 1**

**Fire 0**

**Reactivity 0**

**Primary Physical and Health Hazards:** Suspect Allergen.

**Caution Statement:** Tobramycin Sulfate 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:** Tobramycin - No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.

Sodium bisulfite - IARC Group 3 (not classifiable as to human carcinogenicity). ACGIH A4 (not classifiable as a human carcinogen). Not listed by NTP or OSHA. Two-year dietary studies conducted with rats demonstrated no evidence of carcinogenicity.

Phenol - IARC Group 3 (not classifiable as to human carcinogenicity). ACGIH A4 (not classifiable as a human carcinogen). Not listed by NTP or OSHA. Two-year carcinogenicity studies conducted by NTP in mice and rats demonstrated no evidence of carcinogenicity.

## 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 overdosage, 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:** None known.

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

## Section 6 - Accidental Release Measures

**Spills:** Prevent further migration into the environment. Use absorbent/adsorbent material to solidify liquids. Sweep up or vacuum. 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:** Clear colorless solution

**Odor:** Odorless

**Boiling Point:** No applicable information found

**Melting Point:** No applicable information found

**Specific Gravity:** No applicable information found

**pH:** 3.5-6.0

**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

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

#### 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/m<sup>3</sup> 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

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

**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

Tobramycin sulfate

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

Phenol

TSCA - Yes

CERCLA - Name on list is phenol or benzene, hydroxy-. RQ = 1000 pounds (454 kg)

SARA 302 - Name on list is phenol. RQ = 1000 pounds (454 kg), TPQ = 500/10000 pounds (227/4540 kg)

SARA 313 - Name on list is phenol. De minimis = 1%

OSHA Substance Specific - No

Sodium bisulfite

TSCA - Yes

CERCLA - Name on list is sodium bisulfite. RQ = 5000 pounds (2270 kg).

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

Edetate disodium

TSCA - Yes

CERCLA - Name on list is ethylenediamine tetraacetic acid. RQ = 5000 pounds (2270 kg)

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)