

Safety Data Sheet

# Tobramycin for Injection, USP

## Section 1: Chemical Product and Company Identification

**Product Name:** Tobramycin

**Chemical Name(s):** D-Streptomine, O-3-amino-3-deoxy- $\alpha$ -D-glucopyranosyl-(1 to 6)-O-[2,6-diamino-2,3,6-trideoxy $\alpha$ -D-ribo-hexapyranosyl-(1 to 4)]-2-deoxy-

**Synonym:** Nebramycin Factor 6

**CAS Number:** 32986-56-4

**RTECS #:** WK2100000

**Trade Name:**

**Chemical Formula:**  $C_{18}H_{37}N_5O_9$



Health	1
Fire	1
Reactivity	0
Personal Protection	E

**Contact Information:**

X-GEN Pharmaceuticals, Inc.  
PO Box 445, Big Flats, NY 14814  
**Technical Assistance:** 607-562-2700  
**Online Assistance:** [www.x-gen.us](http://www.x-gen.us)

**Emergency phone number:**

National Poison Control  
1-800-222-1222

\*\*For information regarding recommended uses and restrictions on usage refer to the product package insert.

## Section 2: Hazard Identification

**Hazard pictograms (GHS-US):**



**Potential Acute Health Effects:** Inhalation, skin contact, ingestion and eye contact may cause irritation or possible allergic reaction.

**Potential Chronic Health Effects:** Hypersensitivity in some people.

**Carcinogenic Effects:** This product is not considered to be a carcinogen by IARC, ACGIH, NTP or OSHA.

**Mutagenic Effects:** Not available

**Teratogenic Effects:** Not available

**Developmental Toxicity:** Suspected of damaging fertility or the unborn child. Tobramycin has been shown to cause total irreversible bilateral congenital deafness as well as kidney damage in the human fetus. Aminoglycosides have been reported to cause kidney toxicity and deafness in the fetus when given to mothers during pregnancy.

**Adverse effects:** May include greatly increased or decreased frequency of urination or amount of urine. Increased thirst, loss of appetite, nausea, vomiting, muscle twitching, numbness, seizures, tingling, auditory ototoxicity, vestibular ototoxicity, skin itching, redness, rash or swelling and headache. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

### Section 3: Composition and Information on Ingredients

#### Principle Components:

<u>Name</u>	<u>CAS #</u>	<u>% by Weight</u>
Tobramycin	32986-56-4	Pure material

### Section 4: First Aid Measures

**General:** Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposure. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. Obtain medical attention.

**Inhalation:** If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

**Skin contact:** Avoid contact. Flush with copious amounts of soap and water. This material may be absorbed through the skin. Seek medical attention immediately.

**Eye contact:** Check for and remove any contacts lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Seek medical attention immediately.

**Ingestion:** DO NOT induce vomiting. Flush mouth out with copious amounts of water. Seek medical attention immediately.

**Notes to physician:** Seek product package insert for complete information.

**Overdose Treatment:** Not available

### Section 5: Fire Fighting Measures

**Flammability of the product:** May combust at high temperatures.

**Combustion Products:** Smoke and toxic fumes, carbon oxides and nitrogen oxides.

**Unusual Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

**Extinguishing Media and instruction:**

**Small fire:** Use DRY chemical powder. **Large fire:** Use water spray, carbon dioxide, fog or foam as appropriate for surrounding fire and materials. DO NOT use water jet.

**Protective equipment & precautions for firefighters:** As with all fires, evacuate personnel to a safe area. Firefighters should wear self-contained breathing apparatus and protective clothing.

**Special remarks on fire hazard:** Not available

**Special remarks on explosion hazard:** Not available

## Section 6: Accidental Release Measures

**Release to land:**

**Small Spill:** Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local, state, and federal regulations.

**Large Spill:** Use a shovel to put the material into a convenient waste disposal container. Sweep up or vacuum with caution to avoid generation of dust during clean-up. Finish cleaning by spreading water on the contaminated surface and clean surface thoroughly to remove residual contamination. Collect in suitable container for disposal. For proper waste disposal, see section 13 of the SDS.

**Release to air:** If dust is generated, wear a disposable dust respirator (N95), and reduce exposures by ventilating area. Clean up spill immediately.

**Release to Water:** Refer to local water authority.

**Protective equipment:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation, avoid inhalation of dust from spilled material. Wear approved respiratory protection, chemically compatible gloves and protective clothing.

## Section 7: Handling and Storage

**Handling:** As a general rule, when handling Tobramycin for Injection, USP, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material.

Keep locked up. Keep away from heat, sources of ignition and oxidizing agents. Empty containers pose a fire risk, evaporate the residue under a fume hood. DO NOT ingest. DO NOT breathe dust. Wear suitable protective clothing. Use only in accordance with directions.

**Storage:** Keep container tightly closed. Keep container in a cool, dry, well ventilated area (see USP CRT storage conditions). Refer to label instructions to ensure product integrity.

**Incompatibilities:** Keep away from strong oxidizing agents.

## Section 8: Exposure Controls / Personal Protection

**Engineering Controls:** Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation or process enclosure. Local exhaust ventilation such as laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing or other dust-generating procedures.

**Personal Protection:** Chemical splash goggles, lab coat, nitrile or natural rubber gloves.

**Respiratory Protection:** Under normal use, respirators are not required. If dusts are generated, use a disposable mask (N95). Personnel wearing respirators should be fit tested and approved for respirator use, under OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Exposure limit:** Not available

## Section 9: Physical and Chemical Properties

**Physical appearance:** Solid powder.

**Color:** White or almost white.

**Molecular Weight:** 467.52

**Taste:** Not available

**Odor:** Odorless

**Odor Threshold:** Not available

**pH:** Not available

**Melting Point:** Approx. 287°C (548°F)

**Freezing Point:** Not available

**Boiling Point:** Not available

**Flash Point:** Not available

**Evaporation rate:** Not available

**Flammability:** Not available

**Upper Flammable Limit:** Not available

**Lower Flammable Limit:** Not available

**Vapor Pressure:** Not available

**Vapor Density:** Not available

**Relative density:** Not available

**Partition Coefficient:** Not available

**Auto-Ignition Temperature:** Not available

**Decomposition Temperature:** Approx. 287°C (548°F)

**Viscosity:** Not available

**Dispersion Properties:** Not available

**Solubility:** Freely soluble in water

## Section 10: Stability and Reactivity

**Reactivity:** Not available

**Chemical stability:** Stable under normal conditions

**Possibility of hazardous reaction:** Not available

**Conditions to avoid:** Light, heat and moisture

**Incompatible materials:** Store away from strong oxidizing agents.

**Hazardous decomposition products:** Emits irritating and/or toxic fumes and nitrogen oxides under fire conditions.

**Corrosivity:** Non-corrosive in presence of glass.

**Polymerization:** Not known to occur.

## Section 11: Toxicological Information

**Routes of exposure:** Ingestion, inhalation, eye contact and skin contact.

**Symptoms:**

**Short term:** Possible eye, skin, gastrointestinal and/or respiratory tract irritation. **Long term:** Possible hypersensitization, superinfection, kidney damage and irreversible hearing damage.

**Reproductive toxicity:** Tobramycin has been shown to cause total irreversible bilateral congenital deafness as well as kidney damage in the human fetus.

**FDA Pregnancy Category:** D

**Toxicity to animals:**

**Oral Rat:** LD50: >7500 mg/kg

**Oral Mouse:** LD50: >11500 mg/kg

**Measures of toxicity:** Not available

**Additional reproductive health and toxicity data is available from the National Institute for Occupational Safety and Health (NIOSH) and/or Registry of Toxic Effects of Chemical Substance (RTECS).**

## Section 12: Ecological Information

**Ecotoxicity:** Not available

**Bioaccumulation potential:** Not available

**Products of biodegradation:** Not available

**Toxicity of the products of biodegradation:** Not available

**Section 13: Disposal Information**

**Waste classification:** Non-Hazardous

**Waste from residues/unused products:** Dispose of waste in accordance with all applicable federal, state and local laws.

**Waste Disposal:** Dispose of waste in accordance with all applicable federal, state and local laws.

**Section 14: Transport Information**

**DOT Classification:** Not a DOT controlled material (United States).

**UN Number:** Not available

**UN Shipping name:** Not available

**Transport hazard class:** Not available

**Packing Group:** Not available

**Environmental hazard:** Not available

**Transport in bulk:** Not available

**Special precautions needed with transport:** Not available

**Section 15: Regulatory Information**

**Federal and State Regulations:**

**Tobramycin TSCA 8(b) inventory:** No components listed

**Other Regulations:** EU EINECS List: This product is on the European Inventory of Existing Commercial Chemical Substances.

**Other Classifications:**

**WHMIS (Canada):** Not controlled under WHMIS (Canada).

**DSCL (EEC):** Not available

**HMIS (U.S.A.):**

**Health Hazard:** 1

**Fire Hazard:** 1

**Reactivity:** 0

**Personal Protection:** E

**National Fire Protection Association (U.S.A.):**

**Health:** 1

**Flammability:** 1

**Reactivity:** 0

**Protective Equipment:** Gloves, lab coat, safety glasses, dust respirator. Be sure to use an approved/certified respirator or equivalent.

**Section 16: Other Information**

**References:** Not available

**Created:** 1/30/2015

**Last Updated:** 3/27/2015

**Prepared & Approved by:** X-GEN Pharmaceuticals, Inc., Safety Committee

*The above information is believed to be accurate and represents the best information currently available to us. The use of this product should be through or under the direction of a physician. This SDS does not address therapeutic use of this material. X-GEN Pharmaceuticals, Inc. makes no warranties, express or implied with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information. In no event should X-GEN Pharmaceuticals be liable for any claim, loss, or damage of any third party, even if X-GEN Pharmaceuticals has been advised of the possibility of such damages to occur.*