SAFETY DATA SHEET

1. Identification

Product Identifier: Tobramycin Ophthalmic Solution, USP 0.3% - Sterile

Synonyms: Nebramycin Factor 6

National Drug Code (NDC): 17478-290-20
17478-290-10

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Not classifiable.

Health Hazards: Harmful if swallowed Category 4

Symbol(s):

Signal Word: Warning.

Hazard Statement(s):

H302 Harmful if swallowed.

Precautionary Statement(s):

P264 Wash hands thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Tobramycin	32986-56-4	Nebramycin Factor 6	$C_{18}H_{37}N_5O_9$	467.52	0.3%

*The formula also contains Benzalkonium Chloride, 0.01% as a preservative; Boric Acid, Sodium Chloride, Sodium Sulfate, Tyloxapol, Sodium Hydroxide and/or Hydrochloric Acid to adjust pH between 7.0 – 8.0 and Purified Water.

4. First Aid Measures

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/ supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation: Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders: Use personal protective equipment (see section 8).

Signs and Symptoms: Not determined.

Medical Conditions Aggravated by Exposure: Allergies to aminoglycoside antibiotics or any component of the product. As with other antibiotic preparations, prolonged use may result in overgrowth of other no susceptible organisms, including fungi. Appropriate

	measures should be taken if this occurs. Reproduction studies, in three different types of animals, at doses up to thirty-three times the normal human systemic dose have revealed no evidence of impaired fertility or harm to the fetus due to tobramycin. There are no adequate and well controlled studies in pregnant women. Tobramycin should be used in pregnancy only if the potential benefits justify the risk to the fetus. Because of the potential for adverse reactions in nursing infants from Tobramycin Ophthalmic Solution, a decision should be made whether to discontinue nursing the infant or discontinue taking the drug, taking into account the importance of the drug to the mother.
Notes to Physician:	Additional details are available on the package insert or in the Physicians' Desk Reference.

5. Firefighting Measures

Suitable Extinguishing Media:	Dry chemical, carbon dioxide, water spray or fog, and foam on surrounding materials.
Unsuitable Extinguishing Media:	Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:	Material emits toxic fumes.
Other Specific Hazards:	Not determined.
Special Protective Equipment Precautions for Firefighters:	Evacuate personnel to safe area. Wear self-contained breathing apparatus and full and protective gear. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.

6. Accidental Release Measures

Personal Precautions:	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
Personal Protective Equipment:	For personal protection see section 8.
Methods for Cleaning Up:	Use personal protective equipment. Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste.
Environmental Precautions:	Product administered to patients presents a negligible impact on the environment.
Reference to Other Sections:	Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Avoid contact with product and use caution to prevent puncturing containers. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store product upright in original containers with the cap tightly closed at a controlled room temperature 20°C – 25°C (68°F – 77°F) Store according to label and/or product insert information.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Tobramycin	Not established.

Engineering Controls: In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process which will maintain the dust and vapor levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Safety Data Sheets.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134). WARNING: Do not use air purifying respirators in oxygen depleted environments.

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Not required for the normal use of this product. Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
Contaminated Equipment:	Wash contaminated clothing separately. Wash equipment with soap and water. Release rinse water into an approved wastewater system or according to Federal, State and Local regulations.

9. Physical and Chemical Properties

Physical State/Color:	Clear, colorless to slightly yellow solution.
Odor:	Odorless.
Odor Threshold:	No data available.
pH:	Approximately 7.0.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	No data available.
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Miscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.
Specific Gravity:	1.0.
% Volatile by Volume:	<1.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Extreme heat or cold. Avoid freezing.
Incompatible Materials:	This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.
Hazardous Decomposition Products:	Toxic fumes when heated to decomposition.
Hazardous Polymerization:	Should not occur.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: May cause irritation to the respiratory tract and hypersensitivity in some individuals.

Ingestion: May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities can cause nausea and vomiting.

Skin Contact: May cause irritation. Repeated or prolonged contact can induce hypersensitivity (anaphylactic) in some individuals.

Eye Contact: Not for injection into the eye. This is an ophthalmic preparation. May cause irritation and hypersensitivity in some individuals. Adverse reactions include localized ocular toxicity, lid itch and swelling and redness of the mucous membrane of the eye (conjunctival erythema). These reactions occur in less than 3% of patients. Signs of overdose of Tobramycin Ophthalmic Solution include inflammation of the cornea (punctate keratitis), erythema, increased tearing (lacrimation), swelling (edema) and lid itching.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity:

Compound	Species	Route	Type	Dose
Tobramycin	Rat	Intravenous	LD_{50}	104 mg/kg
Boric Acid	Rat	Oral	LD_{50}	2,660 mg/kg
Boric Acid	Rat	Inhalation	LC_{50}	16 mg/L

Tobramycin: May cause irritation to the eyes, skin and respiratory tract; can cause hypersensitivity (anaphylactic) in some individuals. May cause localized ocular toxicity including itching, swelling and conjunctival erythema.

Benzalkonium Chloride: It may cause eye and skin irritation. Harmful if swallowed. It causes gastrointestinal/digestive tract irritation and burn. It may affect behavior (central nervous system depression, depression) and metabolism. May produce burning pains in the mouth, throat, and abdomen, profuse salivation, and muscle weakness. May also affect the respiratory system and cardiovascular system, liver and kidneys. Inhalation may

	cause respiratory tract and mucous membrane irritation with sore throat, coughing, shortness of breath, and delayed lung edema. May affect material (mutagenic) and may cause adverse reproductive effects. Prolonged or repeated skin contact may cause dermatitis. Repeated or prolonged exposure may cause allergic reactions in sensitive individuals. May cause cyanosis of skin and lips cause by lack of oxygen.
Boric Acid:	Inhalation may cause coughing and chest discomfort. Prolonged skin contact can cause burns and sensitization. Ingestion can cause nausea and vomiting. Swallowing large quantities may be fatal and chronic exposure can cause central nervous system stimulation and skin redness or rash.
Acute Toxicity – Dermal:	No data available.
Corrosivity:	No data available.
Dermal Irritation:	No data available.
Eye Irritation:	No data available.
Sensitization:	No data available.
Toxicokinetics/Metabolism:	No data available.
Target Organ Effects:	Eyes, skin and digestive tract.
Reproductive Effects:	No data available.
Carcinogenicity:	No data available.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.
Mutagenicity:	No data available.
Aspiration Hazard:	No data available.
Chronic Effects:	May cause irritation and hypersensitivity (anaphylactic in some individual. Prolonged use of topical antibiotics can give rise to overgrowth of nonsusceptible organisms, including fungi. Bacterial resistance to Tobramycin may also develop.

12. Ecological Information

Ecotoxicity

Aquatic:	No data available.
Terrestrial:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

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

US Federal Regulations:

Toxic Substance Control Act (TSCA):	Not listed.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

California Proposition 65:	Not listed.

16. Other Information

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