

**SDS: GENTAK® Gentamicin Sulfate Ophthalmic Ointment,
USP 0.3% - Sterile**

SAFETY DATA SHEET

1. Identification

Product Identifier: GENTAK® Gentamicin Sulfate Ophthalmic Ointment, USP 0.3% - Sterile

Synonyms: Gentamicin Sulfate Ophthalmic Ointment, USP 0.3%; Gentamicin Sulfate; 0-3-Deoxy-4-C-methyl-3(methylamino)-β-L-arabinopyranosyl-(1-> 6 -O-[2,6-diamino-2,3,4,6-tetradeoxy-α-D-erythro-hexopyranosyl-(1->4)]-2-deoxy-D-streptamine (sulfate salt).

National Drug Code (NDC): 17478-284-35

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:

Respiratory sensitization	Category 1
Skin sensitization	Category 1
Reproductive toxicity	Category 2



Symbol(s):

Signal Word: Warning.

Hazard Statement(s):

H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361	Suspected of damaging fertility or the unborn child.

Precautionary Statement(s):

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.

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- P261 Avoid breathing dust/fume/gas/mist/
vapors/ spray.
- P272 Contaminated work clothing should not
be allowed out of the workplace.
- P280 Wear protective gloves/protective
clothing/eye protection/face protection.
- P302: IF ON SKIN: Wash with plenty of
+ water.
P352
- P333 If skin irritation or rash occurs: Get
+ medical advice/attention.
P313
- P362 Take off contaminated clothing and
+ wash it before reuse.
P364
- P304 IF INHALED: Remove person to fresh
+ air and keep comfortable for breathing.
P340
- P304 IF INHALED: Call a POISON CENTER/
+ doctor/physician.
P311
- P308 IF exposed or concerned: Get medical
+ advice/attention.
P313
- P321 Specific treatment (see Section 4).
- P405 Store locked up.
- P501 Dispose of contents/container in
accordance with local/provincial/federal
regulations.

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

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3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
0-3-Deoxy-4-C-methyl-3(methylamino)-β-L-arabinopyranosyl-(1-> 6 -0-[2,6-diamino-2,3,4,6-tetradeoxy-α-D-erythro-hexopyranosyl-(1->4)]-2-deoxy-D-streptamine (sulfate salt); (Gentamicin Sulfate is a complex aminoglycoside antibiotic substance with three components, sulfates of gentamicin C1, gentamicin C2 and gentamicin C1A).	1505-41-0	Gentamicin Sulfate	Not applicable	Not applicable	0.3%

*The formula also contains White Petrolatum and Mineral Oil, with Methylparaben and Propylparaben as preservatives.

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.



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Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Loss of hearing; ringing, buzzing, or feeling of fullness in the ears; change in frequency or amount of urination; increased thirst; loss of appetite; seizures; numb or tingling sensations; muscle twitching; dizziness; nausea; vomiting; clumsiness or unsteadiness; and skin rash, itching, redness, or swelling. Possible allergic reaction to material if inhaled, ingested or in contact with skin.
Medical Conditions Aggravated by Exposure:	Pre-existing hypersensitivity to gentamicin sulfate or related products; pre-existing ocular, renal, auditory or gastrointestinal ailments; pregnancy.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media: Use extinguishing media for type of surrounding fire.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: These products include carbon oxides, nitrogen oxides and toxic fumes.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment/Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Dike ahead of liquid spills for later disposal. Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.



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7. Handling and Storage

Precautions for Safe Handling: 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 according to label and/or product insert information. Store away from oxidizers, acids, and bases.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Gentamicin Sulfate	No data available.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

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).

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: 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: Protective laboratory coat, apron, or disposable garment.

9. Physical and Chemical Properties

Physical State/Color: Semi-solid/ Colorless to light yellowish translucent.
Odor: No data available.
Odor Threshold: No data available.
pH: No data available.
Melting Point: No data available.
Freezing Point: No data available.
Boiling Point: No data available.

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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.

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):	No data available.
Incompatible Materials:	Oxidizers, acids, and bases.
Hazardous Decomposition Products:	No data available.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation:	May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May be harmful if absorbed through the skin. May cause irritation.
Eye Contact:	May cause eye irritation.
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.

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Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Gentamicin Sulfate	Rat	Oral	LD ₅₀	630 mg/kg
Gentamicin Sulfate	Mouse	Oral	LD ₅₀	>11,269 mg/kg
Mineral Oil	Rat	Oral	LD ₅₀	>5,000 mg/kg
Petrolatum	Rat	Oral	LD ₅₀	>5,000 mg/kg
Methylparaben	Mouse	Oral	LD ₅₀	>8,000 mg/kg
Propylparaben	Mouse	Oral	LD ₅₀	>6,332 mg/kg

Acute Toxicity – Dermal: No data available.

Acute Toxicity – Inhalation: No data available.

Corrosivity: No data available.

Dermal Irritation: No data available.

Eye Irritation: No data available.

Sensitization: Prolonged or repeated exposure (via ingestion, inhalation or skin contact) may cause allergic skin and/or respiratory reactions in certain sensitive individuals.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: Aminoglycosides are associated with significant nephrotoxicity and/or ototoxicity (ears, kidneys, nerves).

Reproductive Effects: Suspected of damaging fertility or the unborn child.

Compound	Study Type	Species	Route	Type	Dose	Effect(s)
Gentamicin sulfate	Embryo/Fetal Development	Rat	Intraperitoneal	LOAEL	375 mg/kg/day	Developmental toxicity
Gentamicin sulfate	Prenatal & Postnatal Development	Rat	Subcutaneous	LOAEL	660 mg/kg/day	Developmental toxicity
Gentamicin sulfate	Prenatal & Postnatal Development	Rat	Subcutaneous	LOAEL	660 mg/kg/day	Neonatal toxicity

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: Due to lack of data, the classification is not possible.

Aspiration Hazard: Based on available data, the classification criteria are not met.

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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):	This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.
CERCLA Hazardous Substance and Reportable Quantity:	Not listed.
SARA 313:	Not listed.
SARA 302:	Not listed.

State Regulations

Massachusetts:	Not listed.
New Jersey:	Gentamicin Sulfate.
Pennsylvania:	Gentamicin Sulfate.
California Proposition 65:	Not listed.



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16. Other Information

Not made with natural rubber latex.

NFPA Rating:

Health: 2
Flammability: 0
Reactivity: 0

HMIS Classification:

Health: 2
Flammability: 0
Physical Hazard: 0

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