



**MSDS: Gentak™
(Gentamicin Sulfate Ophthalmic Ointment, 0.3%)**

Manufacturer: Akorn
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Section 1 - IDENTIFICATION

TRADE NAME: Gentak® (gentamicin sulfate ophthalmic ointment, USP), 0.3%
NDC # 17478-284-35

Description: Colorless to light yellowish translucent ointment

Composition	CAS#	TLV (mg/m³)	PEL (mg/m³)	%Content
Gentamicin Sulfate, Sterile	1405-41-0	NE	NE	0.3
Methylparaben	99-76-3	NE	NE	0.05
Propylparaben	94-13-3	NE	NE	0.01
Petrolatum (Fonoline)	8009-03-8	NE	NE	89
Mineral Oil (Kaydol)	8042-47-5	NE	NE	10

Common name of active ingredients: Gentamicin Sulfate
Chemical Formula: N/A

Section 2 – HAZARDOUS INGREDIENTS

Principal Hazardous Ingredients: Gentamicin Sulfate

% Threshold Limit Value: NE

Carcinogenicity: NE

NTP: No

IARC: No

OSHA: No

NE= Not established

< = Greater Than
> = Less Than

Section 3 – PHYSICAL AND CHEMICAL CHARACTERISTICS

Physical State:	Semi solid	Odor:	Odorless
Appearance:	Colorless to light yellowish translucent ointment		
Boiling Point:	NE	Vapor Density (air = 1):	NE
Vapor Pressure (mm Hg):	NE	Viscosity at 25° C:	NE
Solubility in Water:	Immiscible		
Specific Gravity:	NE	Volatile:	NE
Evaporation Rate:	NE	Reactivity in Water:	NE
pH:	NE	Melting Point:	NE
Latex Free:	Yes	NE= Not established	

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Section 4 – FIRE AND EXPLOSION HAZARD DATA

Extinguisher Media: Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

Explosion: This material is assumed to be combustible.

Fire Fighting Instructions: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Section 5 – REACTIVITY DATA

Stability: Stable

Incompatibility: NE.

Hazardous Decomposition Products: May emit toxic fumes under fire conditions.

Conditions to Avoid: Avoid exposure to light and heat.

Hazardous Polymerization: Should not occur

Section 6 – HEALTH HAZARDS

Adverse Effects: Adverse effects may include 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.

Overdose Effects: High doses pose a greater risk of ear nerve damage and kidney toxicity.

Acute: Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

Chronic: Possible hypersensitization and hearing loss.

Chemical Listed as Carcinogen or Potential Carcinogen: None

National Toxicology Program: No **I.A.R.C Monographs:** No

OSHA: No **OSHA Permissible Exposure Limit:** NE

ACGIH Threshold Limit Value: NE **NE= Not established**

1. **Inhalation:** May cause irritation. Remove to fresh air.
2. **Eyes:** May cause irritation. Flush with copious quantities of water.
3. **Skin:** May cause irritation, super infections, and can be absorbed through the skin. Avoid contact. Flush with copious quantities of water.
4. **Ingestion:** May cause irritation. Flush out mouth with water. This material is poorly absorbed from the gastrointestinal tract.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, impaired kidney function, myasthenia gravis, parkinsonism, and eighth-cranial-nerve impairment.

Cross Sensitivity: Individuals sensitive to one aminoglycoside antibiotic may be sensitive to this material also.



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Pregnancy Comments: Adequate and well-controlled pregnancy studies in humans have not been done, and studies in rats and rabbits have not shown that Gentamicin causes adverse effects on the fetus. Some other aminoglycosides have been reported to cause deafness in the fetus.

Section 7 – SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

Handling/Storage: Do not handle and store near heat, light, oxidants and bases. Store at 20° – 25° C (68° – 77° F)

Neutralizing Chemical Agent: Not relevant

Steps to be taken in case material is released or spilled: Assure slippery conditions are nullified. Spread sand or dust. Scoop up and remove. Wash the area with soap and cleaner.

Waste Disposal Methods: Dispose of waste in accordance with all applicable Federal, State and local laws.

Section 8 – PROTECTION INFORMATION

Engineering Controls: Personal involved in handling the raw material in compounding process should use adequate personal protective equipment, e. g. NIOSH approved respirator, goggles, gloves and protective clothing. Ensure training in the handling of chemical material and use of current Material Safety Data Sheets.

Airborne Exposure Limits:

NE

Ventilation:

No special ventilation requirements

Skin Protection:

Protect exposed skin and wear rubber gloves.

Eye Protection:

Safety glasses

Respiratory Protection:

General ventilation

Section 9 – TOXICOLOGY INFORMATION

LD₅₀ (Acute oral toxicity of): Gentamicin Sulfate

LD₅₀ rat, oral >5 grams/kg

LD₅₀ >11269 mg/kg

LD₅₀ rat, intravenous = 96 mg/kg

LD₅₀ rat, intramuscular = 384 mg/kg

LD₅₀ mouse, intravenous = 47 mg/kg

Section 10 – ECOLOGICAL INFORMATION

Ecotoxicity: Not established

BOD₅ and COD: Not available

Environmental fate information: NE

Other Precautions: None

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