

MSDS: Gentak™
(Gentamicin Sulfate Ophthalmic Solution, USP 0.3%)

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Section 1 - IDENTIFICATION

TRADE NAME: GENTAK™ Gentamicin Sulfate Ophthalmic Solution, USP, 0.3%
Description: GENTAK™ is a 3mg/mL sterile aqueous ophthalmic solution of gentamicin sulfate indicated in the topical treatment of ocular bacterial infections, including conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharoconjunctivitis, acute meibomianitis, and dacryocystitis.

| Composition | CAS# | TLV (mg/m³) | PEL (mg/m³) | %Content |
|---------------------------|-------------|-------------------------------|-------------------------------|-----------------|
| Gentamicin Sulfate, USP | 1405-41-0 | NE | NE | 0.3 |
| Disodium Phosphate, USP | 7782-85-6 | NE | NE | 0.55 |
| Monosodium Phosphate, USP | 10049-21-5 | NE | NE | 0.01 |
| Sodium Chloride, USP | 7647-14-5 | NE | NE | 0.74 |
| Benzalkonium Chloride, NF | 8001-54-5 | NE | NE | 0.10 |
| Purified Water | 7732-18-5 | NE | NE | qs |

The pH range is between 6.5 and 7.5.

Common name of active ingredient: Gentamicin Sulfate, USP

Molecular Formula: Gentamicin is a mixture of the sulfate salts of Gentamicin C₁, C₂, and C_{1A}

Gentamicin C₁: C₂₁H₄₃N₅O₇

Gentamicin C₂: C₂₀H₄₁N₅O₇

Gentamicin C_{1A}: C₁₉H₃₉N₅O₇

Molecular Weight (free base):

Gentamicin C₁ = 477.6 g/mole

Gentamicin C₂ = 463.6 g/mole

Gentamicin C_{1A} = 449.5 g/mole

Legal Category: Prescription Only

Section 2 - HAZARDOUS INGREDIENTS

Principal Hazardous Ingredient: Gentamicin Sulfate
Emergency Overview: White Dropper Bottle in a cardboard box.
Clear, colorless, odorless solution. For eyes only.
Carcinogenicity: NE **Mutagenicity:** NE
Teratogenicity: NE **Developmental Toxicity:** NE
NTP: NE **IARC:** NE
OSHA: NE



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Section 3 - PHYSICAL AND CHEMICAL CHARACTERISTICS

| | | | |
|--------------------------------|---------------------------|------------------------------------|-------------|
| Appearance and color: | Clear, colorless solution | | |
| Boiling Point: | NE | Melting/Freezing Point: | NE |
| Vapor Pressure (mm Hg): | NE | Vapor Density: | NE |
| Evaporation Rate: | NE | Percent Volatile by Volume: | <1 |
| Solubility in water: | Miscible | pH: | 6.5 and 7.5 |
| Specific Gravity: | 1.0 @ 25°C | Latex Free: | Yes |

Section 4 - FIRE AND EXPLOSION HAZARD DATA

| | | | |
|--|--|----------------------------|----|
| Flash Point: | NE | Flash Point Method: | NE |
| Auto Ignition Temperature: | NE | Method: | NE |
| Extinguisher Media: | Carbon dioxide, dry chemical, halon, foam, water spray or fog as appropriate for surrounding fire and materials | | |
| Products of Combustion: | Sulfur oxides (SO ₂ , SO ₃) and fumes | | |
| Special Firefighting Procedures: | Wear protective clothing and self-contained breathing apparatus. Use water spray to keep fire exposed containers cool. Do not spray water into the burning material. | | |
| Special Remarks on Fire Hazards: | NA | | |
| Special Remarks on Explosion Hazards: | NA | | |

Section 5 - REACTIVITY DATA

| | |
|--|---|
| Chemical Stability: | Stable |
| Stability Conditions to Avoid: | Extreme cold or heat |
| Incombatability: | Strong acids, bases, alkali metals, alkali hydrides |
| Special Remarks on Reactivity: | NA |
| Special Remarks on Reactivity: | NA |
| Hazardous Decomposition Products: | NA |
| Hazardous Polymerization: | Will not occur |

Section 6 - HEALTH HAZARDS

Eye: May cause irritation and hypersensitivity (anaphylaxis) in some individuals. May cause burning, swelling of the inner eyelid (non-specific conjunctivitis), conjunctival epithelial defects, and increased blood flow in the inner eyelid (conjunctival hyperemia). Other rare effects include an abnormal decrease in blood clotting platelets with hemorrhages (thrombocytopenic purpura) and hallucinations.

Skin: May cause irritation, and repeated or prolonged contact can induce hypersensitivity (anaphylaxis) in some individuals.

Ingestion: May cause irritation and hypersensitivity in some individuals. Ingestion of large quantities may induce gastric disturbances.

Inhalation: May cause irritation and induce hypersensitivity in some individuals.

Chronic Effects: May cause irritation and hypersensitivity (anaphylaxis) in some individuals. Prolonged use of topical antibiotics may give rise to overgrowth of nonsusceptible organisms, including fungi. Bacterial resistance to gentamicin may also develop. Bacterial and fungal corneal ulcers have developed during treatment with gentamicin ophthalmic preparations.

Target Organs: Eyes, kidneys and digestive tract

Medical Conditions Aggravated by Long Term Exposure: Allergies to aminoglycoside antibiotics or any component of the product. As with other antibiotic preparations, prolonged use may result in overgrowth of other nonsusceptible organisms, including fungi. Appropriate measures should be taken if this occurs. Gentamicin has been shown to depress body weights, kidney weights and median glomerular counts in newborn rats when administered systemically to pregnant rats in daily doses. There are no adequate and well-controlled studies in pregnant women, so gentamicin should be used only if the potential benefits justify the risk to the fetus.

Potential Acute Health Effects: Very hazardous in case of skin contact (irritant), eye contact (irritant), ingestion, and inhalation. Hazardous in case of skin contact (permeator). Inflammation of the eye is characterized by redness, watering, and itching. Skin inflammation is characterized by itching, scaling, redness, or, occasionally blistering.

Emergency and First Aid Procedures:

- Eyes:** If not prescribed this medication, rinse with copious amounts of water for at least 20 minutes. Contact a physician.
- Inhalation:** Remove from source of exposure and into fresh air. If victim is not breathing, clear airway and immediately begin artificial respiration. Seek medical attention immediately.
- Skin:** Remove from source of exposure. Remove all contaminated clothing and wash skin with copious amounts of water for at least 20 minutes. Contact a physician if skin becomes irritated.
- Ingestion:** Wash out mouth and give plenty of water and bland fluids. Seek medical attention immediately.
- Note to physicians:** Treat symptomatically and supportively

Section 7 - PROTECTION INFORMATION

Engineering Controls: Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal Protection: Splash goggles. Lab coat. Thick impermeable gloves. Vapor respirator. Be sure to use an approved/certified respirator or equivalent for handling raw materials. No respiratory protection is required in the clinical or home environment.

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.

Exposure Limits: Not available

Section 8 - SPECIAL PRECAUTIONS AND SPILL/LEAK PROCEDURES

Steps to be taken in case material is released or spilled: Wear respiratory protection and protective clothing. Absorb with inert material, and containerize prior to disposal in accordance with local, state, and federal regulations. Use personal protective equipment recommended in section 7.

Waste Disposal Methods: Dispose of in accordance with county, regional, federal, state, and local regulations.

Handling: Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.

Storage: Store at 15° to 30°C

Section 9 - DISPOSAL CONSIDERATIONS

Waste Disposal Methods:

Observe all federal, state, and local environmental regulations for disposal guidelines.

Appropriate Method of Disposal of Product, Preparation, Packaging:

Disposal must be made according to official regulations. Consult state, local and national governmental requirements.

Section 10 - TOXICOLOGY INFORMATION

Summary of Risks: Toxicological information refers to the raw materials of the product. Concentrations and toxicological effects are substantially reduced in the product. For more detailed information see MSDS on chemical material CAS# 1405-41-0 for Gentamicin Sulfate. May cause irritation or allergic reactions by inhalation, ingestion, skin and eye contact. Should be avoided by persons with an allergy to aminoglycoside antibiotics.



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Section 11 - ECOLOGICAL INFORMATION

Ecotoxicity: Product as administered to patients presents negligible impact on the environment.

Section 12 - REGULATORY INFORMATION

DOT Designations: Not classified as Hazardous by DOT regulations
EPA Designations: RCRA Hazardous waste (40 CFR 261.33) Not listed
FDA Designations: Prescription only medication

Section 13 - TRANSPORT INFORMATION

Transportation Data: Not classified as Hazardous by DOT regulations

OTHER INFORMATION

Legend: NE = Not Established
NA = Not Available

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