

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078928135

N/A

# SAFETY DATA SHEET

## Gentamicin Sulfate Ophthalmic Solution, USP 0.3% – Sterile

### 1. IDENTIFICATION

<b>Product Identifier:</b>	Gentamicin Sulfate Ophthalmic Solution, USP 0.3% – Sterile
<b>Synonyms:</b>	Gentamicin C complex sulfate
<b>National Drug Code (NDC):</b>	17478-283-10
<b>Recommended Use:</b>	Pharmaceutical. Gentamicin Sulfate Ophthalmic Solution is indicated for the treatment of ocular bacterial infections including, conjunctivitis, keratitis, keratoconjunctivitis, corneal ulcers, blepharitis, blepharoconjunctivitis, acute meibomianitis, and dacryocystitis.
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
<b>Contact Telephone:</b>	1-800-932-5676
<b>E mail:</b>	customer.service@akorn.com
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Not classifiable.	
<b>Health Hazards:</b>	Skin Sensitization	Category 1
	Respiratory Sensitization	Category 1
	Reproductive Toxicity	Category 1



**Symbol(s):**

**Signal Word:**

Danger.

**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):**

- P261 Avoid breathing dust/fume/gas/mist/vapors/spray.
- P272 Contaminated work clothing should not be allowed out of the workplace.

# SAFETY DATA SHEET

## Gentamicin Sulfate Ophthalmic Solution, USP 0.3% – Sterile

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

P308 IF exposed or concerned: Get medical advice/attention.  
+  
P313

P405 Store locked up.

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

**Hazards Not Otherwise Classified:**  
**Supplementary Information:**

None.  
None.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Gentamicin Sulfate	Gentamicin C complex sulfate	1405-41-0	No data available	No data available	0.3%

The formula also contains Benzalkonium Chloride as preservative; Disodium Phosphate; Monosodium Phosphate and Sodium Chloride. The pH range is from 6.8 to 7.3.

### 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.

## SAFETY DATA SHEET

### Gentamicin Sulfate Ophthalmic Solution, USP 0.3% – Sterile

<b>Eye Contact:</b>	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.
<b>Skin Contact:</b>	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.
<b>Inhalation:</b>	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.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	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.
<b>Medical Conditions Aggravated by Exposure:</b>	Pre-existing hypersensitivity to gentamicin sulfate or related products; pre-existing ocular, renal, auditory or gastrointestinal ailments; pregnancy.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

#### 5. FIREFIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use water, carbon dioxide, dry chemical or water spray.
<b>Unsuitable Extinguishing Media:</b>	Not determined.

#### Specific Hazards Arising from the Chemical

<b>Hazardous Combustion Products:</b>	None known.
<b>Other Specific Hazards:</b>	Closed containers may explode from the heat of fire.

# SAFETY DATA SHEET

## Gentamicin Sulfate Ophthalmic Solution, USP 0.3% – Sterile

### Special Protective Equipment and 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:

Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations. Wipe working area surfaces to dryness, and then wash with soap and water.

### 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.

## 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 at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

### Specific End Use:

Pharmaceutical drug product.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Occupational Exposure Guidelines:

Ingredient	Type	Value
Gentamicin Sulfate	Not established	Not established

### 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).

## SAFETY DATA SHEET

### Gentamicin Sulfate Ophthalmic Solution, USP 0.3% – Sterile

**Eyes Protection:**

Not required for the normal use of this product. 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 should be worn when working with large quantities. 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:**

Not required for the normal use of this product. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

**General Hygiene Considerations:**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State/Color:**

Clear colorless liquid solution.

**Odor:**

No data available.

**Odor Threshold:**

No data available.

**pH:**

6.8 to 7.3.

**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):**

Soluble 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

# SAFETY DATA SHEET

## Gentamicin Sulfate Ophthalmic Solution, USP 0.3% – Sterile

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	Will not occur.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Extreme heat or cold. Do not freeze.
<b>Incompatible Materials:</b>	Strong oxidizers.
<b>Hazardous Decomposition Products:</b>	Carbon monoxide (CO), Carbon dioxide (CO <sub>2</sub> ).

### 11. TOXICOLOGICAL INFORMATION

#### Information on the Likely Routes of Exposure

<b>Inhalation:</b>	May be harmful if inhaled. May cause respiratory tract irritation.
<b>Ingestion:</b>	May be harmful if swallowed.
<b>Skin Contact:</b>	May cause skin irritation. Repeated or prolonged contact can induce hypersensitivity (anaphylactic) in some individuals.
<b>Eye Contact:</b>	May cause eye irritation.
<b>Symptoms Related to the Physical, Chemical and Toxicological Characteristics:</b>	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.
<b>Delayed and Immediate Effects of Exposure:</b>	Low blood pressure, respiratory depression, central nervous system depression, bradycardia, tachycardia, coma.

#### Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Gentamicin Sulfate	Rat	Oral	LD <sub>50</sub>	630 mg/kg
	Mouse	Oral	LD <sub>50</sub>	>11,269 mg/kg

# SAFETY DATA SHEET

## Gentamicin Sulfate Ophthalmic Solution, USP 0.3% – Sterile

### Irritation / Sensitization

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

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

### Repeated Dose Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
Gentamicin Sulfate	Reproductivity	Rat	No route specified	50 mg/kg/day	No test specified	Fetotoxic
		Rat	No route specified	75 mg/kg/day	No test specified	Reduced birth weights and other adverse effects in offspring
		Mouse	No route specified	10 mg/kg/day	No test specified	Fetotoxic
		Guinea Pig	No route specified	4 mg/kg/day	No test specified	Transient abnormalities in fetus

### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

#### Aspiration Hazard:

No data available.

#### Toxicokinetics/Metabolism:

No data available.

#### Target Organ Effects:

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

#### Systemic Effects:

No data available.

#### Reproductive Effects:

Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women.

#### 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.



# SAFETY DATA SHEET

Gentamicin Sulfate Ophthalmic Solution, USP 0.3% – Sterile

## 12. ECOLOGICAL INFORMATION

### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

**Terrestrial Toxicity:** 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

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

## 14. TRANSPORT INFORMATION

**Department of Transportation (DOT):** Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
No applicable	No applicable	No applicable	No applicable

## 15. REGULATORY INFORMATION

### US FEDERAL REGULATIONS

**Toxic Substance Control Act (TSCA):**

Ingredient	Inventory
Gentamicin Sulfate	No

**CERCLA Hazardous Substance:**

Ingredient	Reportable Quantity
Not applicable	Not applicable



## SAFETY DATA SHEET

### Gentamicin Sulfate Ophthalmic Solution, USP 0.3% – Sterile

#### EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

#### U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Gentamicin Sulfate	Listed	Listed	Not Listed

#### California Proposition 65:

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

#### 16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

**Disclaimer:** This document is generated to distribute health, safety and environmental data. It is not a specification sheet and none of the displayed data should be construed as a specification. Information on this SDS sheet was obtained from sources which we believe are reliable, and we believe that the information is complete and accurate. However, the information is provided without any warranty, express or implied, regarding its correctness. Some of the information presented and conclusions drawn are from sources other than direct test data of the substance. The conditions or methods of handling, storage, use and disposal of the product are beyond our control and may also be beyond our knowledge. It is the user's responsibility to determine the suitability of any material for a specific purpose and to adopt such safety precautions as may be necessary. If the product is used as a component in another product, this SDS information may not be applicable. For these reasons, we do not assume any responsibility and expressly disclaim liability for any loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of this product.