Section 1 - IDENTIFICATION

Common/Trade Name: Gentamicin Sulfate Ophthalmic Solution, USP, 0.3%

Chemical Names: Gentamicin sulfate

Chemical Formula: Gentamicin is a mixture of the sulfate salts of Gentamicin C1, C2, and C1A
- Gentamicin C1: $\text{C}_{21}\text{H}_{43}\text{N}_{5}\text{O}_{7}$
- Gentamicin C2: $\text{C}_{20}\text{H}_{41}\text{N}_{5}\text{O}_{7}$
- Gentamicin C1A: $\text{C}_{19}\text{H}_{39}\text{N}_{5}\text{O}_{7}$

Category: Prescription only

Section 2 – HAZARD(S) IDENTIFICATION

Routes of Entry: Eyes, kidneys and digestive tract

Carcinogenicity:
- NTP: No
- IARC: No
- OSHA Regulated: No

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.

Section 3 – COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS#</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gentamicin Sulfate, USP</td>
<td>1405-41-0</td>
<td>0.3%</td>
</tr>
<tr>
<td>Disodium Phosphate, USP</td>
<td>7782-85-6</td>
<td>0.55%</td>
</tr>
<tr>
<td>Monosodium Phosphate, USP</td>
<td>10049-21-5</td>
<td>0.01%</td>
</tr>
</tbody>
</table>
Section 4 – FIRST AID MEASURES

Eyes: If not prescribed this medication, rinse with copious amounts of water for at least 20 minutes. Contact a physician.

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.

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.

Ingestion: Wash out mouth and give plenty of water and bland fluids. Seek medical attention immediately.

Section 5 – FIRE FIGHTING MEASURES

Flash Point: NE

Auto ignition: NE

Lower Explosion Limit: NE

Upper Explosion Limit: NE

General Hazard: NE

Fire Fighting Instructions: Wear protective clothing and self-contained breathing apparatus. Use water spray to keep fire exposed containers cool.

Fire Fighting Equipment: Carbon dioxide, dry chemical, halon, foam, water spray or fog as appropriate for surrounding fire and materials.

Hazardous Combustion Products: Sulfur oxides (SO₂, SO₃) and fumes.

Section 6 – ACCIDENTAL RELEASE MEASURES

Clean-Up: Wear respiratory protection and protective clothing. Absorb with inert material, and containerize prior to disposal in accordance with local, state, and federal regulations.

Section 7 – HANDLING AND STORAGE

Precautions: Avoid contact with product and use caution to prevent puncturing containers.

General Handling: No special protective equipment or procedures are required in the clinical or home environment.

Storage Conditions: Store at 15° to 30°C
### Section 8 – EXPOSURE CONTROLS / PERSONAL PROTECTIVE

**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.

**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.

**Personal Protective Equipment**

<table>
<thead>
<tr>
<th>Eye Protection:</th>
<th>Splash goggles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hand Protection:</td>
<td>Thick permeable gloves</td>
</tr>
<tr>
<td>Respiratory Protection:</td>
<td>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.</td>
</tr>
<tr>
<td>Skin Protection:</td>
<td>Lab coat</td>
</tr>
</tbody>
</table>

**Exposure Limits:** NE

### Section 9 – PHYSICAL/ CHEMICAL CHARACTERISTICS

<table>
<thead>
<tr>
<th>Physical Form/ Appearance:</th>
<th>Clear, colorless solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point/Boiling Range:</td>
<td>NE</td>
</tr>
<tr>
<td>Melting Point/Melting Range:</td>
<td>NE</td>
</tr>
<tr>
<td>Freezing Point:</td>
<td>NE</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NE</td>
</tr>
<tr>
<td>Relative Vapor Density:</td>
<td>NE</td>
</tr>
<tr>
<td>Percent Volatiles by volume:</td>
<td>&lt;1</td>
</tr>
<tr>
<td>pH:</td>
<td>6.5 to 7.5</td>
</tr>
<tr>
<td>Molecular Weight (free base):</td>
<td>Gentamicin C1 = 477.6 g/mole</td>
</tr>
<tr>
<td></td>
<td>Gentamicin C2 = 463.6 g/mole</td>
</tr>
<tr>
<td></td>
<td>Gentamicin C1A = 449.5 g/mole</td>
</tr>
<tr>
<td>Solvent Solubility:</td>
<td>Miscible in water</td>
</tr>
<tr>
<td>Latex Free:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Section 10 – STABILITY AND REACTIVITY

**Reactivity:** NE

**Chemical Stability:** Stable

**Possibility of Hazardous Reactions:** Strong acids, bases, alkali metals, alkali hydrides
Conditions to Avoid: Extreme cold or heat
Hazardous Polymerization: Will not occur

Section 11 – TOXICOLOGICAL INFORMATION

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.

Medical Conditions Aggravated by Accidental 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.

Acute Toxicity: 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.

Section 12 – ECOLOGICAL INFORMATION

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

Biodegradable: NE

Section 13 – DISPOSAL INFORMATION

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

Section 14 – TRANSPORT INFORMATION

UN/NA Nimber: NE
U.S. DOT Hazard Class: Not classified as Hazardous by DOT regulations
Proper Shipping Name: NE
Shipping Label: NE
Section 15 – REGULATORY INFORMATION

FDA (Food & Drug Administration): Prescription only medication
TSCA (Toxic Substance Control Act): NE
HMIS (Hazardous Materials Information System (USA)): NE
WHMIS (Workplace Hazardous Materials): NE

Section 16 – OTHER INFORMATION

Date of preparation or last revision: 04-13

Key to Abbreviations:
NE = Not Established
NA = Not Available

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