



## SAFETY DATA SHEET

### 1 – IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY UNDERTAKING

Product Name: **Gentamicin Sulfate, USP with Betamethasone Valerate, USP (Gentacalm Topical Spray)**

Formula / Product Code: FN-0063

Chemical description/Application: Antimicrobial Solution

Supplier: **American Pharmaceuticals and Cosmetics, Inc.**  
 1401 Joel East Road  
 Ft Worth, TX 76140

Emergency Phone: (817) 293-6363 Ext 112

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### 2 – HAZARD(S) IDENTIFICATION



**Warning - Combustible**



**Potential Acute Health Effects :**

Mild irritation to nose and throat, plus possible nausea, headache, vomiting, narcosis and CNS depression if inhaled. Mild irritation to the skin. Eye contact may cause irritation and burning sensations with possible eye damage. Ingestion may cause gastrointestinal disturbances, nausea, headache, vomiting and CNS depression; plus loss of hearing or unusual sensations in the ears.



**Potential Chronic Health Effects:**

Carcinogenic Effects – None Known  
 Mutagenic Effects – Possible DNA inhibition or cytogenic effects  
 Teratogenic Effects – Hypercorticism  
 Developmental Effects – Possible fetotoxicity (not death)

### 3 – COMPOSITION / INFORMATION ON INGREDIENTS

The composition of this product is proprietary. Hazardous ingredients are listed below.

Information on hazardous ingredients:

<u>Name</u>	<u>Cas No.</u>	<u>Exposure Limits</u>	<u>Toxicological Data</u>
Gentamicin Sulfate	1405-41-0	N/A	LD <sub>50</sub> = >5000 mg/kg (Oral – rat)
Betamethasone Valerate	2152-44-5	IHGV=24 mg/m <sup>3</sup>	LD <sub>50</sub> = >3000 mg/kg (Oral – rat)
Isopropyl Alcohol	67-63-0	OSHA PEL = 400 ppm ACGIH TLV = 400 ppm	LD <sub>50</sub> = 933 mg/kg (PR – mouse)
Propylene Glycol	57-55-6	N/A	LD <sub>50</sub> = 6423 mg/kg (IV – rat)



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### 4 – FIRST AID MEASURES


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- INHALATION:** Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.
- EYE CONTACT:** Flush with plenty of water for at least 15 minutes, keeping eyelids open. Obtain medical attention.
- SKIN CONTACT:** Immediately wash skin with soap and plenty of water.
- INGESTION:** Induce vomiting and wash mouth out with water. Obtain medical attention.

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### 5 – FIRE FIGHTING MEASURES

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- FLAMMABILITY:**  Combustible
- FLASH POINT:** 200°F (93.3°C)
- AUTO-IGNITION TEMPERATURE:** Not Available
- FLAMMABLE LIMITS:** Not Determined
- PRODUCTS OF COMBUSTION:** Emits toxic fumes, including oxides of sulfur
- UNUSUAL FIRE AND EXPLOSION HAZARDS:** Vapors may flow along surfaces to distant ignition sources and flash back.
- EXTINGUISHING MEDIA:** Water spray. Carbon dioxide, dry chemical powder, or appropriate foam.
- SPECIAL FIRE-FIGHTING PROCEDURES:** Wear self-contained breathing apparatus, if available, and protective clothing. Move exposed containers from fire area if it can be done without risk. Use water to keep fire-exposed containers cool.

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### 6 – ACCIDENTAL RELEASE MEASURES

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Isolate hazard area. Keep unnecessary and unprotected personnel away. Caution! Floors may become slippery.

**GENERAL PROCEDURES:** Wear suitable protective clothing. Ventilate area and shut off ignition sources.

**LAND SPILL:** For a small spill, absorb with towels or mop, transfer to a suitable disposal container or rinse to drain. For large spills, absorb with inert material, such as ChemSorb®, Toxi-Dri® or other commercial absorbent, dry sand, or vermiculite. Scoop into a closed container for disposal. Remove sources of ignition.

Clean up spills and leaks to prevent soil and water contamination. Contact the appropriate regulatory authorities.



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### 7 – HANDLING AND STORAGE

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Empty containers will retain product residue (liquid and/or vapors).

**HANDLING:**

Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Avoid contact with eyes. Empty containers retain product residue (liquid and/or vapor), and can be dangerous. Keep container tightly closed. Avoid contact with heat, sparks and flames. Avoid ingestion and inhalation.

**STORAGE:**

Keep away from heat, sparks, and flame. Keep away from sources of ignition. Store in a tightly closed container. Store in a cool, dry, well-ventilated area.

Storage Conditions: Store upright between 2°C and 30°C (36°F and 86°F).

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### 8 – EXPOSURE CONTROLS / ACCIDENTAL RELEASE MEASURES

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**ENGINEERING CONTROLS:**

Use adequate general or local exhaust ventilation to keep airborne concentrations below permissible exposure limits for isopropyl alcohol.

**EXPOSURE LIMITS:**

(ACHIG, NIOSH, OSHA)  
TLV = 400 ppm  
PEL = 400 ppm

**PERSONAL PROTECTION:**

Eyes – Wear appropriate protective eyeglasses or chemical safety goggles  
Skin – Appropriate protective gloves recommended  
Respiratory – For exposure above permissible limits, wear an approved chemical-cartridge respirator.

**ADDITIONAL PROTECTIVE MEASURES:**

Employers should supply safety shower and eye bath. Wash thoroughly after handling. Wash contaminated clothing before reuse.

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### 9 – PHYSICAL AND CHEMICAL PROPERTIES

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<b>Vapor Pressure:</b>	Not Available	<b>Vapor Density:</b>	Not Available
<b>Solubility in Water:</b>	Miscible	<b>Physical State:</b>	Liquid
<b>pH:</b>	3.0 to 4.5	<b>Bulk Density:</b>	0.99 g/mL
<b>Freezing Point:</b>	Not Determined	<b>Boiling Point:</b>	Not Determined
<b>Appearance &amp; Odor:</b>	Colorless to light yellow with odor of isopropyl alcohol.		





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### 10 – STABILITY AND REACTIVITY

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<b>GENERAL:</b>	Stable.
<b>INCOMPATIBLE MATERIALS:</b>	Strong oxidizing agents
<b>CONDITIONS TO AVOID:</b>	Extreme heat, ignition sources.
<b>HAZARDOUS POLYMERIZATION:</b>	Will not occur.
<b>CORROSIVITY:</b>	Not Corrosive
<b>HAZARDOUS DECOMPOSITION PRODUCTS:</b>	Carbon monoxide, carbon dioxide

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### 11 – TOXICOLOGICAL INFORMATION

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<b>TOXICITY:</b>	Oral LD <sub>50</sub> = > 10,000 mg/kg (mouse, rat) Interperitoneal LD <sub>50</sub> = > 5,500 mg/kg (mouse) Intravenous LD <sub>50</sub> = > 10,000 mg/kg (rat)
<b>IRRITATION:</b>	Mild skin irritation in human Moderate eye irritation
<b>CARCINOGENICITY:</b>	None
<b>CHRONIC TOXICITY:</b>	Possible target organ effects  Central Nervous System: Neurotoxicity, including numbness and convulsions.  Kidneys: Nephrotoxicity  Other Effects: Hypothalamic – pituitary – adrenal axis suppression, manifestations of Cushing's syndrome, hyperglycemia and glucosuria.

**REPRODUCTIVE EFFECTS:** Active ingredient has shown various teratogenic, mutagenic, and other reproductive effects in animal studies. Little if any effects from product exposure are expected.

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### 12 – ECOLOGICAL INFORMATION

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No data available.

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### 13 – DISPOSAL CONSIDERATIONS

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Material not listed under RCRA regulations Classification and documentation is required before disposing. Follow all local, state, and federal regulations.



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## 14 – TRANSPORTATION INFORMATION

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**PROPER SHIPPING NAME:** None  
**HAZARD CLASS:** NA  
**IDENTIFICATION NUMBER:** NA  
**DOT EMERGENCY GUIDE #:** NA  
**REPORTABLE QUANTITY (RQ):** None

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## 15 – REGULATORY INFORMATION

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**OSHA Status:** This product is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200

**TSCA Status:** This product is a food, food additive, drug, cosmetic or device as defined by Section 201 of the Federal Food, Drug and Cosmetic Act and therefore, is exempt from TSCA regulation under Section 3 (2) (B) (vi)

**CERCLA Reportable Quantity:** None

**SARA Title III:**

**Section 302:** No ingredients meet reportable quantity criteria

**Section 313:** This product contains listed chemicals: Isopropyl Alcohol

**Clean Air Act:** No hazardous air pollutants

**Clean Water Act:** None of the chemicals in this product are listed as hazardous.

**RCRA Status:** If discarded in its purchased form, this product would not be a hazardous waste, either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste.

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## 16 – OTHER INFORMATION

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Hazard Rating (NFPA 704M)

Health	Flammability	Reactivity	Other
1	2	0	0

0 = Insignificant    1 = Slight    2 = Moderate    3 = High    4 = Extreme

No other regulatory or hazard information is currently available.  
This product should be used only according to label directions.



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### 16 – OTHER INFORMATION *continued*

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The data contained herein is based on current information that American Pharmaceuticals and Cosmetics, Inc. believes to be reliable.

Important changes were made in section(s): Revised format to new SDS format

Previous Revision # and Date: 09/28/12, Rev. 1.0

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### Notice

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The data contained herein is based on current information that American Pharmaceuticals and Cosmetics, Inc. believes to be reliable. However, no expressed or implied warranty is made with regard to the accuracy of such data or its suitability for a given situation. Such data relates only to specific product described and not to such product in combination with any other product and no agent of American Pharmaceuticals and Cosmetics, Inc. is authorized to vary any of such data. American Pharmaceuticals and Cosmetics, Inc. disclaims all liability for any actions taken or foregone upon such data.