SAFETY DATA SHEETS

This SDS packet was issued with item:

078908128

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078908129 078908130

MATERIAL SAFETY DATA SHEET

Preparation Date: 9/28/12
Replaces Version Dated: New
Version 1.0

Section 1 – Product and Company Information

Product Name: **Gentamicin Sulfate, USP with Betamethasone Valerate, USP (GENTACALM) Topical Spray**
Product Code:
Supplier: **American Pharmaceuticals and Cosmetics, Inc.**
1401 Joel East Road
Ft Worth, TX 76140

Chemical Family: Aminoglycoside Antibiotic/Corticosteroid
Emergency Phone: (817) 293-6363 Ext 112
Fax: (817) 293-2952

Section 2 - Composition/Information on Ingredients

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

Information on hazardous ingredients:

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

Section 3 - Hazards Information

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)

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Section 4 – First Aid Measures

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.

Inhalation – Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

Ingestion – Induce vomiting and wash mouth out with water. Obtain medical attention.

Section 5 – Fire Fighter Measures

Flammability of the Product – Combustible

Auto-Ignition Temperature – Not Available

Flash Point - 200ºF (93.3ºC)

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.

Section 6 – Accidental Release Measures

General Procedures – Wear suitable protective clothing. Ventilate area and shut off ignition sources.

Spill Clean-up - 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.

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Section 7 – Handling and Storage

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 – Store upright between 2°C and 30°C (36°F and 86°F) in a dry, well-ventilated area. Keep away from heat, sparks, and flame. Keep away from sources of ignition. Store in a tightly closed container.

Section 8 – Exposure Controls / Personal Protection

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 Protective Equipment

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.

Section 9 – Physical and Chemical Properties

Physical State – Mobile liquid

Color – Colorless

Odor – Odor of isopropyl alcohol

pH – 3.0 to 4.5

Boiling Point – Not Determined

Freezing Point – Not Determined

Solubility in Water – Miscible

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Bulk Density – 0.99 g/mL

Vapor Pressure – Not Available

Vapor Density – Not Available

Section 10 – Stability and Reactivity

Chemical Stability – Stable

Conditions to Avoid – Extreme heat, ignition sources

Incompatibility with Other Materials – Strong oxidizing agents

Corrosivity – Not Corrosive

Hazardous Decomposition Products – Carbon monoxide, carbon dioxide

Hazardous Polymerization – Will not occur

Section 11 – Toxicological Information

Toxicity Oral LD_{50} = > 10,000 mg/kg (mouse, rat)

Interperitoneal LD_{50} = > 5,500 mg/kg (mouse)

Intravenous LD_{50} = > 10,000 mg/kg (rat)

Carcinogenicity – None

Chronic Toxicity - 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.

Irritation – Mild skin irritation in human
Moderate eye irritation

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Section 12 – Ecological Information

Data for product not available

Section 13 – Disposal Considerations

Material not listed under RCRA regulations. Dispose of in accordance with all local, state and federal regulations.

Section 14 – Transport Information

DOT Classification: Not a DOT controlled material (United States)

Identification: Not Applicable

Special Provisions
For Transport: Not Applicable

No other information for domestic or international shipping is available.

Section 15 – Regulatory Information

- 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 be 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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Section 16 – Other Information

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.

Storage Conditions: Store upright between 2ºC and 30ºC (36ºF and 86ºF).

Notice to Reader

All chemicals may pose unknown hazards and should be used with caution. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this MSDS. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this MSDS is based on technical data judged to be reliable, **American Pharmaceuticals and Cosmetics, Inc.** assumes no responsibility for the completeness or accuracy of the information contained herein.

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