

SAFETY DATA SHEET

Gentamicin Sulfate Topical Spray

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, Australian WorkSafe, Japanese Industrial Standard JIS Z 7250:2000, and European Directives

1. PRODUCT IDENTIFICATION

1.1 TRADE NAME (AS LABELED):	Gentamicin Sulfate Topical Spray
SYNONYMS:	Not available
CAS#:	Mixture
1.2 PRODUCT USE:	Antibiotic / Steroid
CHEMICAL SHIPPING NAME/CLASS:	Non-Regulated
U.N. NUMBER:	N/A
1.3 MANUFACTURER'S NAME:	First Priority, Inc.
ADDRESS:	1590 Todd Farm Drive, Elgin, IL 60123-1287
BUSINESS PHONE:	800-650-4899
EMERGENCY PHONE:	800-424-9300 (Chemtrec U.S. – 24 Hrs)
WEB SITE:	www.prioritycare.com
DATE OF CURRENT REVISION:	July 4, 2015
DATE OF LAST REVISION:	New

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW: This product is a clear, colorless liquid with an Isopropyl Alcohol odor.

Health Hazards: Repeated or prolonged exposure may cause irritation to skin. Can be absorbed through the skin. May cause irritation to eyes upon contact. May cause respiratory irritation upon inhalation. Vapors may cause drowsiness and/or dizziness. May be harmful if ingested.

Flammability Hazards: This product is not a combustible liquid.

Reactivity Hazards: None known

Environmental Hazards: The Environmental effects of this product have not been investigated.

US DOT SYMBOLS

Not-Regulated

CANADA (WHMIS) SYMBOLS

Complies with WHMIS 2015

EUROPEAN and (GHS) Hazard Symbols



Signal Word: **Warning!**

2.1 GHS LABELING AND CLASSIFICATION:

CLASSIFICATION OF SUBSTANCE OR MIXTURE IN ACCORDANCE WITH 29 CFR 1200 (OSHA HCS) AND THE EUROPEAN UNION DIRECTIVES:

This product does meet the definition of a hazardous substance or preparation as defined by 29 CFR 1910. 1200 AND the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

EU HAZARD CLASSIFICATION OF INGREDIENTS PER DIRECTIVE 1272/2008/EC:

Index Number:

EC# 231-791-2 This substance is not classified in the Annex VI of Directive 67/548/EEC

EC# 200-661-7 Annex VI Index# 603-117-00-0

EC# 200-338-0 This substance is not classified in the Annex VI of Directive 67/548/EEC

EC# 215-765-8 This substance is not classified in the Annex VI of Directive 67/548/EEC

EC# 218-439-3 This substance is not classified in the Annex VI of Directive 67/548/EEC

Substances not listed either individually or in group entries must be self classified.

Component(s) Contributing to Classification(s)

All Ingredients

2.2 LABEL ELEMENTS:

GHS Hazard Classification(s):

Eye Irritant Category 2A

Hazard Statement(s):

H319: Causes serious eye irritation

Precautionary Statement(s):

P280: Wear protective gloves/eye protection/face protection.

P264: Wash thoroughly after handling.

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2.3 HEALTH HAZARDS OR RISKS FROM EXPOSURE:

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The most significant routes of overexposure for this product are by contact with skin or eyes, inhalation and ingestion. The symptoms of overexposure are described below.

ACUTE:

INHALATION: Inhalation of mist or spray may cause respiratory irritation. Vapors can cause drowsiness and/or dizziness.

CONTACT WITH SKIN: Prolonged or repeated contact may cause irritation. May be absorbed through the skin

EYE CONTACT: Contact may cause eye irritation.

INGESTION: Under normal conditions of intended use, this material is not expected to be an ingestion hazard. Ingestion may cause gastrointestinal irritation, nausea and vomiting.

CHRONIC: Prolonged or repeated exposure can be irritating to mucous membranes, skin, and respiratory system. Can cause liver and kidney damage.

TARGET ORGANS: Acute: Eyes, Skin, Respiratory tract **Chronic:** Cardiovascular system, Kidney, Liver

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Hazardous Ingredients:	WT%	CAS#	EINECS #	GHS Hazard Classification
Water	60 - 72%	7732-18-5	231-791-2	Not Classified
Isopropyl Alcohol	16 - 20%	67-63-0	200-661-7	H225 Flam Liq Cat 2, H319 Eye Irrit Cat 2, H336 STOT SE Cat 3
Propylene Glycol	16 - 20%	57-55-6	200-338-0	Not Classified
Gentamicin Sulfate	TRADE SECRET *	1403-66-3	215-765-8	Not Classified
Betamethasone Valerate	TRADE SECRET *	2152-44-5	218-439-3	Not Classified
Balance of other ingredients is less than 1% in concentration (or 0.1% for carcinogens, reproductive toxins, or respiratory sensitizers).				

NOTE: This product has been classified in accordance with the hazard criteria of the CFR and the SDS contains all the information required by the CFR, EU Directives and the Japanese Industrial Standard *JIS Z 7250: 2000*.

* Ingredient concentration are Company Trade Secret - Business Confidential. First Priority is withholding the specific chemical percentages under provision of the OSHA Hazard Communication Rule Trade Secrets (1910.1200(i)(1)). The specific chemical percentages will be made available to health professionals in accordance with 29 CFR 1910.1200 (i)(1) (2) (3) (4)..

4. FIRST-AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES:

EYE CONTACT: If product enters the eyes, open eyes while under gentle running water for at least 15 minutes. Seek medical attention if irritation persists or blurred vision occurs.

SKIN CONTACT: Wash skin thoroughly with soap and water after handling. Seek medical attention if irritation develops and persists.

INHALATION: If breathing becomes difficult, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention.

INGESTION: If product is swallowed, call physician or poison control center for most current information. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or who cannot swallow. Seek medical advice. Take a copy of the label and/or SDS with the victim to the health professional.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Some individuals may develop skin sensitization from exposure.

4.2 SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Inhalation of vapors may cause drowsiness or dizziness.

4.3 RECOMMENDATIONS TO PHYSICIANS:

Treat symptoms and eliminate overexposure.

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5. FIRE-FIGHTING MEASURES

5.1 FIRE EXTINGUISHING MATERIALS:

FIRE EXTINGUISHING MATERIALS: Use fire extinguishing methods below:

Water Spray: No Carbon Dioxide: Yes
 Foam: Yes Dry Chemical: Yes
 Halon: Yes Other: Any "C" Class

5.2 UNUSUAL FIRE AND EXPLOSION HAZARDS:

This product is not a flammable liquid. Keep containers tightly closed when not in use. Vapors may travel to source of ignition and flash back.

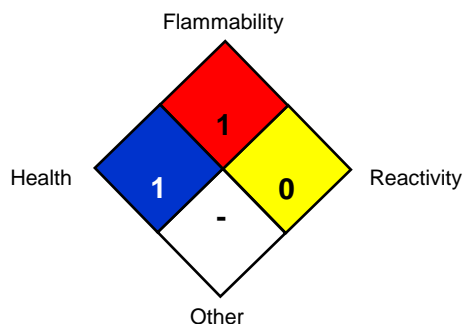
Explosion Sensitivity to Mechanical Impact: No

Explosion Sensitivity to Static Discharge: Yes

5.3 SPECIAL FIRE-FIGHTING PROCEDURES:

Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Isolate materials not yet involved in the fire and protect personnel. Move containers from fire area if this can be done without risk; otherwise, cool with carefully applied water spray. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

NFPA RATING SYSTEM



HMIS RATING SYSTEM

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM			
HEALTH HAZARD (BLUE)			1
FLAMMABILITY HAZARD (RED)			1
PHYSICAL HAZARD (YELLOW)			0
PROTECTIVE EQUIPMENT			
EYES	RESPIRATORY	HANDS	BODY
	See Sect 8		See Sect 8
For Routine Industrial Use and Handling Applications			

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES:

Do not inhale vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition.

6.2 ENVIRONMENTAL PRECAUTIONS:

Stop leak. Contain spill if possible and safe to do so. Prevent product from entering drains.

6.3 SPILL AND LEAK RESPONSE:

Stop the flow of material, if this can be done safely. Dike and contain the spill with inert material (sand, earth, fuller's earth, etc.) and if appropriate, transfer the liquid and solid dike material to containers for disposal. Remove contaminated clothing promptly and wash affected skin areas with soap and water. Wash clothing before reuse. Keep spill out of all sewers and open bodies of water. Dispose of in accordance with U.S. Federal, State, and local hazardous waste disposal regulations and those of Canada and its Provinces, those of Australia, Japan and EU Member States (see Section 13, Disposal Considerations).

7. HANDLING and STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING:

Use good hygiene practices. As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after handling this product. Use good hygiene practices.

7.2 STORAGE AND HANDLING PRACTICES:

Store in original container. Keep container closed. Store in a cool, dry location. Avoid exposure to ignition sources and incompatible materials.

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7.3 SPECIFIC USES:

See section 1.2 for details.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

8.1 EXPOSURE PARAMETERS:

Chemical Name	CAS#	ACGIH TLV	OSHA TWA
Water	7732-18-5	Not Listed	Not Listed
Isopropyl Alcohol	67-63-0	200 ppm	500 ppm
Propylene Glycol	57-55-6	Not Listed	Not Listed
Gentamicin Sulfate	1403-66-3	Not Listed	Not Listed
Betamethasone Valerate	2152-44-5	Not Listed	Not Listed

8.2 EXPOSURE CONTROLS:

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation to ensure exposure levels are maintained below the limits provided above.

The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132) or equivalent standard of Canada, or standards of EU member states (including EN 149 for respiratory PPE, and EN 166 for face/eye protection), and those of Japan. Please reference applicable regulations and standards for relevant details.

RESPIRATORY PROTECTION: Maintain airborne contaminant concentrations below guidelines listed above. If necessary, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, or EU member states.

EYE PROTECTION: Safety glasses or chemical splash goggles are recommended to avoid contact. If necessary, refer to U.S. OSHA 29 CFR 1910.133, Canadian Standards, and the European Standard EN166, Australian Standards, or relevant Japanese Standards.

HAND PROTECTION: Chemical resistant gloves are recommended to prevent contact. If necessary, refer to U.S. OSHA 29 CFR 1910.138, the European Standard DIN EN 374, the appropriate Standards of Canada, Australian Standards, or relevant Japanese Standards.

BODY PROTECTION: Use as appropriate to prevent skin contact. If necessary, refer to appropriate Standards of Canada, or appropriate Standards of the EU, Australian Standards, or relevant Japanese Standards. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136.

9. PHYSICAL and CHEMICAL PROPERTIES

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

APPEARANCE (Physical State) and COLOR: This product is a clear, colorless liquid.

ODOR: Isopropyl Alcohol odor.

ODOR THRESHOLD: Not Available

pH: 3.0 – 4.5

MELTING/FREEZING POINT: 23°F (-6°C)

BOILING POINT: Not Available

FLASH POINT: Not Available

EVAPORATION RATE (n-BuAc=1): Not Available

FLAMMABILITY (SOLID, GAS): Non-Flammable

UPPER/LOWER FLAMMABILITY OR EXPLOSION LIMITS: Not Available

VAPOR PRESSURE (mm Hg @ 20°C (68°F): Not Available

VAPOR DENSITY: Not Available

RELATIVE DENSITY: Not Available

DENSITY: Not available

SPECIFIC GRAVITY: 1.00

SOLUBILITY IN WATER: Miscible

WEIGHT PER GALLON: 8.33 lbs/gal (3.8 kg/gal)

PARTITION COEFFICIENT (n-octanol/water): Not Available

AUTO-IGNITION TEMPERATURE: Not Available

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DECOMPOSITION TEMPERATURE: Not Available

VISCOSITY: Not Available

VOC g/l / Lb/gal: 1.3 lbs/gal – 1.7 lbs/gal (155.8 g/L – 203.7 g/L)

9.2 OTHER INFORMATION:

No additional information available.

10. STABILITY and REACTIVITY

10.1 REACTIVITY:

This product is not reactive.

10.2 STABILITY:

Stable under conditions of normal storage and use.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS:

Will not occur.

10.4 CONDITIONS TO AVOID:

Incompatible materials, excessive heat.

10.5 MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE:

Strong oxidizing agents, Acid anhydrides, Aluminum, Halogenated compounds

10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

Thermal decomposition products include carbon dioxide, carbon monoxide in varying quantities.

11. TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

TOXICITY DATA:

No LD₅₀ Data Available

SUSPECTED CANCER AGENT: One of the ingredients within this product are found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, or CAL/OSHA and therefore are considered to be, or suspected to be, cancer-causing agents by these agencies.

Isopropyl Alcohol CAS# 67-63-0: IARC Group 3: Not Classifiable as to its carcinogenicity to humans.

IRRITANCY OF PRODUCT: This product may be irritating to skin, eyes or respiratory system.

SENSITIZATION TO THE PRODUCT: This product is not a sensitizer

REPRODUCTIVE TOXICITY INFORMATION: No information concerning the effects of this product and its components on the human reproductive system.

SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE: Not Available

SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE: Prolonged exposure can be irritating to mucous membranes, skin and respiratory system.

ASPIRATION HAZARD: None

12. ECOLOGICAL INFORMATION

12.1 TOXICITY:

No toxicity data available.

12.2 PERSISTENCE AND DEGRADABILITY:

No specific data available on this product.

12.3 BIOACCUMULATIVE POTENTIAL:

No specific data available on this product.

12.4 MOBILITY IN SOIL:

No specific data available on this product.

12.5 RESULTS OF PBT AND vPvB ASSESSMENT:

No specific data available on this product.

12.6 OTHER ADVERSE EFFECTS:

No specific data available on this product.

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

12.7 WATER ENDANGERMENT CLASS:

Not water endangering in accordance with EU Guideline 91/155-EWG.

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12.8 SPECIFIC AVAILABLE COMPONENT INFORMATION:

No additional data available.

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS:

Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations, those of Canada, Australia, EU Member States and Japan.

13.2 EU Waste Code:

Not determined

14. TRANSPORTATION INFORMATION

US DOT, IATA, IMO, ADR:

U.S. DEPARTMENT OF TRANSPORTATION (DOT) SHIPPING REGULATIONS: This product is classified (per 49 CFR 172.101) by the U.S. Department of Transportation, as follows:

14.1 PROPER SHIPPING NAME: Not-Regulated

14.2 HAZARD CLASS NUMBER and DESCRIPTION: N/A

14.3 UN IDENTIFICATION NUMBER: N/A

14.4 PACKING GROUP: N/A

14.5 DOT LABEL(S) REQUIRED: N/A

NORTH AMERICAN EMERGENCY RESPONSE GUIDEBOOK NUMBER: N/A

RQ QUANTITY: None

14.6 MARINE POLLUTANT: The components of this product are not designated by the Department of Transportation to be Marine Pollutants (49 CFR 172.101, Appendix B).

14.7 SPECIAL PRECAUTIONS FOR USER:

None

14.8 INTERNATIONAL TRANSPORTION:

INTERNATIONAL AIR TRANSPORT ASSOCIATION SHIPPING INFORMATION (IATA): This product is not considered as dangerous goods.

INTERNATIONAL MARITIME ORGANIZATION SHIPPING INFORMATION (IMO): This product is not considered as dangerous goods.

14.9 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND IBC CODE:

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is considered by the United Nations Economic Commission for Europe to be non-dangerous goods.

15. REGULATORY INFORMATION

15.1 UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

SARA 313 Reporting: Alcohol CAS# 67-63-0

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lbs (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITY (RQ): None

U.S. TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory or are exempted from listing.

OTHER U.S. FEDERAL REGULATIONS: None

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): Ingredients within this product are not on the Proposition 65 Lists.

15.2 CANADIAN REGULATIONS:

CANADIAN DSL/NDSL INVENTORY STATUS: The components of this product are on the DSL Inventory, or are exempted from listing.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS:

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This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all of the information required by those regulations.

CANADIAN WHMIS CLASSIFICATION and SYMBOLS: Complies with WHMIS 2015.

15.3 EUROPEAN ECONOMIC COMMUNITY INFORMATION:

This product does meet the definition of a hazardous substance or preparation as defined by the European Union Council Directives 67/548/EEC, 1999/45/EC, 1272/2008/EC and subsequent Directives.

See Section 2 for full Details.

15.4 AUSTRALIAN INFORMATION FOR PRODUCT: The components of this product are listed on the International Chemical Inventory list.

15.5 JAPANESE INFORMATION FOR PRODUCT:

JAPANESE MINISTER OF INTERNATIONAL TRADE AND INDUSTRY (MITI) STATUS: The components of this product are not listed as Class I Specified Chemical Substances, Class II Specified Chemical Substances, or Designated Chemical Substances by the Japanese MITI.

JAPANESE ENCS INVENTORY: The components of this product are on the ENCS Inventory as indicated in the section on International Chemical Inventories, below.

POISONOUS AND DELETERIOUS SUBSTANCES CONTROL LAW: No component of this product is a listed Specified Poisonous Substance under the Poisonous and Deleterious Substances Control Law.

15.6 INTERNATIONAL CHEMICAL INVENTORIES:

Listing of the components on individual country Chemical Inventories is as follows:

Asia-Pac: Listed

Australian Inventory of Chemical Substances (AICS): Listed

Korean Existing Chemicals List (ECL): Listed

Japanese Existing National Inventory of Chemical Substances (ENCS): Listed

Philippines Inventory of Chemicals and Chemical Substances (PICCS): Listed

Swiss Giftlist List of Toxic Substances: Listed

U.S. TSCA: Listed

16. OTHER INFORMATION

PREPARED BY: Paul Eigbrett – (**GHS MSDS Compliance PLUS**)

DATE OF PRINTING: July 4, 2015

The information contained herein is believed to be accurate but is not warranted to be so. Data and calculations are based on information furnished by the manufacturer of the product and manufacturers of the components of the product. Users are advised to confirm in advance of the need that information is current, applicable and suited to the circumstances of use. First Priority, Inc assumes no responsibility for injury to vendee or third party person proximately caused by the material if reasonable safety procedures are not adhered to as stipulated in the data sheet. Furthermore, First Priority, Inc. assumes no responsibility for injury caused by abnormal use of this material even if reasonable safety procedures are followed.

END OF SDS SHEET