SAFETY DATA SHEETS

This SDS packet was issued with item:

078695228

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

078942844

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

078695236 078695244

MED-PHARMEX™

SAFETY DATA SHEET

GENTAMICIN SULFATE WITH BETAMETHASONE VALERATE OTIC SOLUTION

SECTION 1: IDENTIFICATION

Product Identifier:	GentaVed Otic Solution
Material Name:	Gentamicin Sulfate with Betamethasone Valerate
Recommended Use:	Veterinary ophthalmic solution used as an antibiotic, anti-inflammatory and antipruritic in dogs and cats.
Restrictions on Use:	Veterinary pharmaceutical ophthalmic solution for use in dogs and cats only.
Manufacturer:	**MED-PHARMEX INC.** 2727 Thompson Creek Road Pomona, CA 91767
Business Hours:	8:30 a.m. to 5: 00 p.m. Pacific Time Monday thru Friday
Telephone Number:	909-593-7875
Emergency Telephone:	If over exposure occurs call your poison control center at 1-800-222-1222 … Human Poison Control Center 1-888-426-4435 … ASPCA Poison Control Center

SECTION 2: HAZARD(S) IDENTIFICATION

Product Description:	Clear liquid with a slight alcohol odor.
Classification of the Substance or Mixture:	Veterinary combination of steroid and antibiotic in an otic solution.
Signal Word:	**WARNING**
Hazard statement(s):	May cause an allergic skin reaction.
Precautionary statement(s):	Avoid breathing dust/fumes/gas/mist/vapors/spray. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. **IF ON SKIN** - Wash with plenty of soap and water. If skin irritation or rash occurs get medical advice/ attention. Wash contaminated clothing before reuse. **IF INHALED** - If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Call a POISON CONTROL CENTER or doctor/ physician. Have this sheet handy for physician and/or Poison Control.

Obtained by Global Safety Management, 1-813-435-5161 - www.GSMSDS.com

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	Concentration
Gentamicin Sulfate	1405-41-0	3 mg/ml
Betamethasone Valerate	2152-44-5	1 mg/ml

Benzyl alcohol as a preservative, glycerin and propylene glycol.

SECTION 4: FIRST AID MEASURES

Description of First Aid Measures:

In case of eye contact: Immediately flush eyes with plenty of water for about 15 minutes. If wearing contact lenses, remove only after initial rinse, and continue rinsing eyes for at least 15 minutes. If irritation occurs or persists, consult a physician.

In case of ingestion: Rinse mouth and have the victim drink plenty of water to dilute the alcohol content. Consult a physician or poison control center immediately.

In case of skin contact: While wearing protective gloves, carefully remove any contaminated clothing, including shoes, and wash skin thoroughly with soap and water. If irritation or symptoms occur or persist, consult a physician.

In case of inhalation: Immediately remove the victim to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

NOTE TO PHYSICIAN: Gentamicin sulfate is a aminoglycoside antibiotic. Allergic reactions may occur in susceptible individuals. Exposure to gentamicin sulfate by individuals already using potent diuretics should be avoided. This product contains betamethasone valerate, a steroid hormone. This product is indicated for the relief and treatment of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatosis. Persons with a prior history of asthma, treatment with systemic steroids, or pre-existing skin conditions, such as acne and dermatitis, may be more susceptible to the adverse effects of steroid exposure. Serious health effects including death have occurred in asthmatic patients during transfer from systemic corticosteroid to topical corticosteroid clinical use.

SECTION 5: FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Carbon dioxide (CO_2), extinguishing powder or water spray.

Flammable Properties and Hazards: Under normal conditions of use, this material does not present a significant fire or explosion hazard.

Flash Pt: No Data Available

Explosive Limits: No Data Available

Autoignition Pt: No Data Available

Fire Fighting Instructions: Wear full protective clothing and self-contained breathing apparatus (SCBA). Use water spray to flush spills away.

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SECTION 6: ACCIDENTAL RELEASE MEASURES

Protective Precautions, Protective Equipment and Emergency Procedures: Wear appropriate personal protective equipment. Keep personnel away from the clean-up area. Avoid dust formation. Avoid breathing dust, vapors, mist or gas. Ensure adequate ventilation. For personal protection see section 8.

Methods and Material for Containment and Clean Up: Wash thoroughly with water spray. Dry chemicals, carbon dioxide is also recommended. All spills should be handled according to site requirements and based on precautions cited in the SDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, vacuuming prior to wet mopping or cleaning is required. Dispose in accordance with local, state and federal regulations regarding health, water and air pollution.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation in places where dust and aerosols are formed.

Conditions for safe storage, including any incompatibilities: Keep container tightly closed in a dry and well ventilated place. Store upright. Store at 2-2 °C (36-77°F) and away from ignition sources. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data is sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Ventilation And Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this SDS.

Personal Protection Equipment:

Eye Protection: Not normally needed during normal use. Use of safety glasses with side shields, goggles or full face protection may be required based on hazard, potential for contact, or level of exposure.

Protection Gloves: For situations in which prolonged skin contact is anticipated gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material.

Respiratory Protection: A respirator is not required for routine conditions of use of this product. Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. If respiratory protection is needed, use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, or Canadian CSA Standard Z94.4-02.

Protective Clothing: During patient administration, use of lightweight cotton gown or other medical attire is recommended. In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on Basic Physical and Chemical Properties:

Appearance: Clear liquid.
Physical States: Solution
Freezing Point: No Data Available
Boiling Point: No Data Available
Flash Point: No Data Available
Explosive Limits: No Data Available
Vapor Pressure: No Data Available
Specific Gravity: No Data Available
Solubility in Water: Miscible
Autoignition Point: No Data Available
Percent Volatile: No Data Available
Odor: Slight alcohol odor.
Odor Threshold: No Data Available
Melting Point: No Data Available
Flammability: No Data Available
Evaporation Rate: No Data Available
Relative Density: No Data Available
Vapor Density: No Data Available
Viscosity: No Data Available
Solubility Notes: No Data Available
Other Information: No Data Available
pH: No Data Available

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions and recommended storage conditions.
Reactivity: No data available
Possibility of Hazardous Reactions: No data available
Conditions to Avoid: Open flames and high temperatures.
Incompatibility: No Data Available
Materials to Avoid: Contact with Acetyl Alcohol or other oxidizing agents may result in reaction.
Hazardous Decomposition Products: No data available

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Toxicological Effects:
The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. Therefore, laboratory or process control systems and appropriate work practices should be in place to minimize the potential for inhalation exposure, skin contact, eye contact, or ingestion when working with this material. Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) is presented.

This product may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. Sulfite sensitivity in the general population is unknown and probably low and is more frequent in asthmatic persons. May cause skin irritation. May cause eye irritation. Gentamicin sulfate has produced significant conjunctival irritation in animals.

Carcinogenicity: No Data Available.

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SECTION 12: ECOLOGICAL INFORMATION

Toxicity: No specific environmental toxicity data available for this formulation.

SECTION 13: Disposal considerations

Waste Disposal Method: Disposal must be in accordance with applicable federal, state, and/or local regulations.

SECTION 14: Transport information

Transport: This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

SECTION 15: Regulatory information

Regulatory Information Statement: No Data Available.

SECTION 16: OTHER INFORMATION

Last Revision Date: January 1, 2015

Disclaimer: The information contained in this Safety Data Sheet is provided in good faith and is accurate to the best of our knowledge. However, the manufacturer assumes no warranties expressed or implied. Users of these products are advised to verify that the information is suitable to their particular purposes prior to their use of them.

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MATERIAL SAFETY DATA SHEET

GENTAMICIN SULFATE WITH BETAMETHASONE VALERATE OTIC SOLUTION

PRODUCT INFORMATION

MANUFACTURER: MED-PHARMEX INC.

ADDRESS: 2727 Thompson Creek Road Pomona CA 91767

TELEPHONE NUMBER: (909) 593-7875
8:30 a.m. To 5:00 p.m. (Pacific Time) Monday thru Friday

TRADE NAME AND SYNONYMS: Gentamicin Otic Solution, (VetBeta-Gen Otic Solution)
7.5 mL, 15 mL and 250 mL

CHEMICAL NAME AND SYNONYMS: Gentamicin Sulfate with Betamethasone Valerate Otic solution for use in dogs and cats.

CHEMICAL FAMILY: Combination of steroid and antibiotic.

FORMULA: Gentamicin Sulfate, Betamethasone Valerate, Ethyl Alcohol.

HAZARDOUS INGREDIENTS

- **GENTAMICIN SULFATE 0.3% W/V**
- **BETAMETHASONE VALERATE 0.1% W/V**
- **ETHYL ALCOHOL 19% W/V**
- **GLACIAL ACETIC ACID 0.25% W/V**

PHYSICAL DATA

BOILING POINT (^oF): Not determined

VAPOR PRESSURE (mm Hg): N/A

VAPOR DENSITY (air=1): Not determined

SOLUBIITY IN WATER: Miscible

APPEARANCE AND ODOR: Clear, colorless liquid with odor of alcohol.

SPECIFIC GRAVITY (H_20=1): Not determined

PERCENT VOLATILE BY VOLUME (%): 19% Ethyl Alcohol

EVAPORATION RATE: Not determined

FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (Method Used): Not determined

FLAMMABLE LIMITS: Not determined

EXTINGUISHING MEDIA: Use dry chemicals, Carbon Dioxide.

SPECIAL FIRE FIGHTING PROCEDURES: Use water spray to flush spills away.

UNUSUAL FIRE AND EXPLOSION HAZARDS: None

Obtained by Global Safety Management, Inc. (www.globalsafetynet.com)

HEALTH HAZARD DATA

THRESHOLD LIMIT VALUE: Not determined

EFFECTS OF OVEREXPOSURE: Ethyl Alcohol may cause eye irritation, headache and drowsiness.

EMERGENCY FIRST AID PROCEDURES:

EYES: Immediately flush eyes with plenty of water for about 15 minutes. Get medical attention.

SKIN: Immediately flush affected area with plenty of water.

INHALATION: Immediately remove victim to fresh air.

INGESTION: Have victim drink plenty of water to dilute the alcohol content. Call a physician or Poison Control Center immediately.

REACTIVITY DATA

STABILITY: Stable (**x**) Unstable ( )

INCOMPATIBILITY (Materials to Avoid):

HAZARDOUS DECOMPOSITION PRODUCTS:

HAZARDOUS POLYMERIZATION: Will Occur ( ) Will Not Occur(**x**)

CONDITIONS TO AVOID: Contact with Acetyl Alcohol or other oxidizing agents may result in reaction.

SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Wash thoroughly with water spray. Dry chemicals, Carbon Dioxide is also recommended.

WASTE DISPOSAL METHOD: Dispose in accordance with local, state and federal regulations regarding health, water and air pollution.

SPECIAL PROTECTION INFORMATION

RESPIRATORY PROTECTION:

VENTILATION: Local exhaust.

PROTECTIVE GLOVES: Wear gloves.

EYE PROTECTION: Wear safety goggles.

OTHER PROTECTIVE EQUIPMENT: Avoid getting on clothing.

SPECIAL PRECAUTIONS

PRECAUTIONS TO BE TAKEN IN HANDLING AND STORING:

OTHER PRECAUTIONS:

NOTE;

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