

**GENTAMICIN SULFATE, BETAMETHASONE VALERATE, AND  
CLOTRIMAZOLE OTIC OINTMENT****SECTION 1: IDENTIFICATION**

<b>Product Identifier:</b>	MalOtic
<b>Material Name:</b>	Gentamicin sulfate USP, Betamethasone Valerate USP and Clotrimazole USP Ointment.
<b>Recommended Use:</b>	Veterinary ointment used as antifungal, antibacterial, and anti-inflammatory in dogs.
<b>Restrictions on Use:</b>	Veterinary pharmaceutical ointment for use in dogs only.
<b>Manufacturer:</b>	<b>MED-PHARMEX INC.</b> 2727 Thompson Creek Road Pomona, CA 91767
<b>Business Hours:</b>	8:30 a.m. to 5: 00 p.m. Pacific Time Monday thru Friday
<b>Telephone Number:</b>	909-593-7875
<b>Emergency Telephone:</b>	If over exposure occurs call your poison control center at 1-800-222-1222 ... Human Poison Control 1-888-426-4435 ... ASPCA Poison Control

**SECTION 2: HAZARD(S) IDENTIFICATION**

<b>Product Description:</b>	Smooth, uniform, white to off-white viscous ointment.
<b>Classification of the Substance or Mixture:</b>	Veterinary combination of an antibiotic, antifungal and anti-inflammatory.
<b>Signal Word:</b>	<b>WARNING</b>
<b>Hazard statement(s):</b>	May cause an allergic skin reaction.
<b>Precautionary statement(s):</b>	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. <b>IF ON SKIN</b> - Wash with plenty of soap and water. If skin irritation or rash occurs, get medical advice/ attention. Wash contaminated clothing before reuse. <b>IF INHALED</b> - 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.

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

Chemical Name	CAS Number	Concentration
Betamethasone Valerate	2152-44-5	1.0 mg/g
Gentamicin Sulfate	1405-41-0	3.0 mg/g
Clotrimazole	23593-75-1	10.0 mg/g

In a mineral oil-based system containing a plasticized hydrocarbon gel.

**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 drink plenty of water. Do not induce vomiting unless under the direction of a medical professional. 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 of skin 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.
- Effects of Overexposure:** May cause eye irritation, and may cause skin irritation.

**NOTE TO PHYSICIAN:** This product contains clotrimazole, a broad spectrum antifungal agent, and betamethasone valerate, a steroid hormone. This product is indicated for the topical treatment of dermal infections. 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 exposure to this product. Serious health effects including death have occurred in asthmatic patients during transfer from systemic corticosteroid to topical corticosteroid clinical use. Gentamicin sulfate is an aminoglycoside antibiotic. Allergic reactions may occur in susceptible individuals. Exposure to gentamicin sulfate by individuals already using potent diuretics should be avoided.

**SECTION 5: FIRE FIGHTING MEASURES**

- Suitable Extinguishing Media:** Carbon dioxide (CO<sub>2</sub>), 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.

## 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 2-25°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 are 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.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### Information on Basic Physical and Chemical Properties:

**Appearance:** Smooth, uniform, white to off-white viscous ointment.

**Physical States:** Ointment

**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:** Practically odorless

**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:** Avoid food products. Oxidizers. Strong acids and bases.

**Hazardous Decomposition Products:** Carbon oxides (COx).

## 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.

## 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.