

# **MATERIAL SAFETY DATA SHEET**

**PRODUCT NAME:**

**VetOne Gentizol**

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# MATERIAL SAFETY DATA SHEET

PRODUCT NAME:  
**TRI-OTIC OINTMENT**

**TRI-OTIC OINTMENT is a combination package of 3 products.**

**Gentamicin Sulfate  
Betamethasone Valerate  
Clotrimazole**

**MANUFACTURER:**  
**Med-Pharmex Inc.**  
**2727 Thompson Creek Road**  
**Pomona, CA 91767**

**TELEPHONE: 909-593-7875**

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# Material Safety Data Sheet

12601 Twinbrook Parkway,  
Rockville, MD 20852 USA

Phone Calls: 301-816-8129  
8 a.m. to 5 p.m. EST Mon. - Fri.

## ATTENTION !

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

## GENTAMICIN SULFATE

Catalog Number: 1289003

Revision Date:

November 17, 2008

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**Common Name:** Gentamicin Sulfate

**Manufacturer:** U. S. Pharmacopeia

**Responsible Party:** Reference Standards Technical Services

**Mailing Address:** 12601 Twinbrook Parkway, Rockville, MD 20852 USA

**Phone:** 301-816-8129

**Hours:** 8 a.m. to 5 p.m. EST Mon. - Fri.

**Product Use:** USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

### SECTION 2 - HAZARD INFORMATION

**EMERGENCY OVERVIEW: Irritant. Allergen.**

**Adverse Effects:** Adverse effects may include loss of hearing; ringing, buzzing, or feeling of fullness in the ears; change in frequency or amount of urination; increased thirst; loss of appetite; seizures; numb or tingling sensations; muscle twitching; dizziness; nausea; vomiting; clumsiness or unsteadiness; and skin rash, itching, redness, or swelling. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** High doses pose a greater risk of ear nerve damage and kidney toxicity.

**Acute:** Eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization, hearing loss, and superinfections.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material, impaired kidney function, myasthenia gravis, parkinsonism, and eighth-cranial-nerve impairment.

**Cross Sensitivity:** Persons sensitive to one aminoglycoside antibiotic may be sensitive to this material also.

**Target Organs:** Ears (cochlea and vestibular system) and kidneys

**For additional information on toxicity, see Section 11.**

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**Common Name:** Gentamicin Sulfate

**Formula:** Mixture

# GENTAMICIN SULFATE

Catalog Number: 1289003

Revision Date:

November 17, 2008

**Synonym:** Gentamicin C complex sulfate

**Chemical Name:** Gentamicin sulfate (salt)

**CAS:** 1405-41-0

**RTECS Number:** LY2625000

**Chemical Family:** Aminoglycoside

**Therapeutic Category:** Antibacterial

**Composition:** Pure Material

## SECTION 4 - FIRST AID MEASURES

**Inhalation:** May cause irritation. Remove to fresh air.

**Eye:** Causes irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

**Skin:** Causes irritation. Avoid contact. Flush with copious quantities of soap and water. This material is not absorbed through intact skin, but can be absorbed through denuded, burned, or granulating areas.

**Ingestion:** May cause irritation. Flush out mouth with water. This material is poorly absorbed from the gastrointestinal tract.

**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

### Note to Physicians

**Overdose Treatment:** Treatment of aminoglycoside overdose should be symptomatic and supportive and may include the following:

1. Administer activated charcoal as a slurry.
2. For mild/moderate allergic reactions, administer antihistamines with or without inhaled beta agonists, corticosteroids, or epinephrine. For severe allergic reactions, treat with oxygen, aggressive airway management, antihistamines, epinephrine, corticosteroids, ECG monitoring, and intravenous fluids.
3. Maintain good urine output with intravenous fluids.
4. Hemodialysis is of questionable value following overdose with normal renal function. Consider dialysis with renal failure.
5. Complexation with intravenous ticarcillin may be effective. [Meditext 2008]

## SECTION 5 - FIREFIGHTING MEASURES

**Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

## SECTION 7 - HANDLING AND STORAGE

**Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

**Storage:** Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. Store in a freezer.

**SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION**

**Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.

**Respiratory Protection:** Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

**Gloves:** Chemically compatible

**Eye Protection:** Safety glasses or goggles

**Protective Clothing:** Protect exposed skin.

**Exposure Limits:** n/f

**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

**Appearance and Odor:** White to buff colored powder; odorless

**Odor Threshold:** n/f

**pH:** 3.5 - 5.5 (4% aqueous solution)

**Melting Range:** 218 - 237° C (decomposes)

**Boiling Point:** n/f

**Flash Point:** n/f

**Autoignition Temperature:** n/f

**Evaporation Rate:** n/f

**Upper Flammability Limit:** n/f

**Lower Flammability Limit:** n/f

**Vapor Pressure:** n/f

**Vapor Density:** n/f

**Specific Gravity:** n/f

**Solubility in Water:** Freely soluble

**Fat Solubility:** n/f

**Other Solubility:** Soluble in ethylene glycol and in formamide; insoluble in alcohol, in acetone, in chloroform, in ether, and in benzene

**Partition Coefficient: n-octanol/water:** n/f

**Percent Volatile:** n/f

**Reactivity in Water:** n/f

**Explosive Properties:** n/f

**Oxidizing Properties:** n/f

**Formula:** Mixture

**Molecular Weight:** n/f

# GENTAMICIN SULFATE

Catalog Number: 1289003

Revision Date:

November 17, 2008

## SECTION 10 - STABILITY AND REACTIVITY

**Conditions to Avoid:** Avoid exposure to light, heat, and moisture.

**Incompatibilities:** n/f

**Decomposition Products:** When heated to decomposition material emits very toxic fumes of SO<sub>x</sub> and NO<sub>x</sub>. Emits toxic fumes under fire conditions.

**Stable?** Yes      **Hazardous Polymerization?** No

## SECTION 11 - TOXICOLOGICAL PROPERTIES

**Oral Rat:** LD50: 630 mg/kg; >5000 mg/kg

**Oral Mouse:** LD50: >11269 mg/kg

**Other Toxicity Data:** n/f

**Irritancy Data:** Rabbit/skin: slight; Rabbit/eye: slight

**Corrosivity:** n/f

**Sensitization Data:** Contact dermatitis following therapeutic use of gentamicin has been reported in medical literature.

**Listed as a Carcinogen by:**      **NTP:** No      **IARC:** No      **OSHA:** No

**Other Carcinogenicity Data:** No

**Mutagenicity Data:** Gentamicin tested negative in the *S. typhimurium* Ames assay, the *B. subtilis* Rec-assay, the *S. cerevisiae* gene conversion assay, and the *E. coli* reverse mutation DNA repair and SOS function assays. Positive results were obtained in the *E. coli* forward mutation and DNA-cell binding assay, the *S. cerevisiae* petite induction assay, the chromosome aberration assay in mouse lung cells, and the sister chromatid exchange in human fibroblasts.

**Reproductive and Developmental Effects:** Some aminoglycosides have been reported to cause deafness in the fetus of children whose mothers used them therapeutically during pregnancy. There was no increase in birth defects in the offspring of pregnant rats administered intramuscular doses up to 50 mg/kg/day, pregnant mice administered subcutaneous doses up to 100 mg/kg/day, and pregnant rabbits administered intramuscular doses up to 4 mg/kg/day. Transient abnormalities occurred in the fetus of guinea pigs given 4 mg/kg during pregnancy. Fetotoxicity occurred in mice at doses of 10 mg/kg/day and higher and in rats at 50 mg/kg/day, and reduced birth weights and other adverse effects occurred in the offspring of rats at 75 mg/kg/day.

## SECTION 12 - ECOLOGICAL INFORMATION

**Ecological Information:** n/f

## SECTION 13 - DISPOSAL CONSIDERATIONS

**Disposal:** Dispose of waste in accordance with all applicable Federal, State and local laws.

## SECTION 14 - TRANSPORT INFORMATION

**Shipping Name:** n/f

**Class:** n/f

**UN Number:** n/f

**Packing Group:** n/f

**Additional Transport Information:** n/f

## SECTION 15 - REGULATORY INFORMATION

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**GENTAMICIN SULFATE****Catalog Number:** 1289003**Revision Date:**November 17, 2008

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**U.S. Regulatory Information:** n/f**International Regulatory Information:** EINECS # 215-778-9

<b>SECTION 16 - OTHER INFORMATION</b>
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**Revision:** 17-Nov-08**Previous Revision Date:** 22-Jan-03

Pharmacia & Upjohn

BETAMETHASONE VALERATE

REVISION DATE: November 21, 1995  
AGENT ID#: 10557

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

COMMON NAME: Betamethasone Valerate  
SYNONYMS:  
Betamethasone Valerate USP  
Betamethasone 17-valerate  
2152-44-5 - CAS NUMBER  
9-fluoro-11,21-dihydroxy-16-methyl-17-((1-oxopentyl)oxy)-pregna-1,4-diene-3,20-dione  
225445 - EDP NUMBER  
U-25,922 - UPJOHN U#  
MOLECULAR FORMULA: C27-H37-F-06  
CHEMICAL FAMILY: Steroid  
MANUFACTURER/SUPPLIER: PHARMACIA & UPJOHN  
7171 PORTAGE RD  
KALAMAZOO, MI 49001-0199  
TELEPHONE NUMBERS:  
(616) 833-5122 - (24 HOURS)  
(616) 833-7555 - (8:00 a.m. - 4:30 p.m.)  
(616) 385-7358 - (SAMPLE REQUEST/TECHNICAL ASSISTANCE)

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT 1:  
COMMON NAME: Betamethasone Valerate  
CHEMICAL NAME: 9-fluoro-11,21-dihydroxy-16-methyl-17-((1-oxopentyl)oxy)-pregna-1,4-diene-3,20-dione  
% BY WEIGHT: Main component.  
CAS NUMBER: 2152-44-5  
EXPOSURE LIMIT(S): Not established.

3. HAZARDS IDENTIFICATION

EFFECTS OF OVEREXPOSURE: Suppression of adrenal gland secretion; Cushing's Syndrome; water retention; electrolyte imbalance; hyperglycemia.  
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Systemic fungal infections.

4. FIRST AID MEASURES

EYES: Flush with water for 15 minutes. Hold eyelids open to assure complete contact with water.  
SKIN: Wash with soap and water. Remove contaminated clothing.  
INHALATION: Remove from exposure. Call a physician.

5. FIRE FIGHTING MEASURES

FLASH POINT: Not applicable.  
LOWER EXPLOSION LIMIT (LEL): Not applicable.  
UPPER EXPLOSION LIMIT (UEL): Not applicable.  
EXTINGUISHING MEDIA: Water, carbon dioxide, or dry chemical.  
FIRE-FIGHTING PROCEDURES: None.  
UNUSUAL FIRE OR EXPLOSION HAZARDS: None.

6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:  
Vacuum or sweep up spillage. Avoid dust.

7. HANDLING AND STORAGE

PRECAUTIONS FOR HANDLING AND STORING: Wear dust respirator and rubber gloves. Wear freshly laundered clothing daily. Harmful if swallowed, inhaled or absorbed through skin.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

RESPIRATORY PROTECTION: Approved respirator.  
VENTILATION:  
LOCAL EXHAUST: Where dust generated.  
PROTECTIVE GLOVES: Rubber.  
EYE PROTECTION: Safety glasses with side shields.  
OTHER PROTECTIVE EQUIPMENT: Arms and face if dusty.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Crystals  
BOILING POINT: Not applicable.  
EVAPORATION RATE: Not applicable.  
MELTING POINT: 183 - 184 deg C (361 - 363 deg F)  
SOLUBILITY IN SOLVENTS: Chloroform-soluble  
SOLUBILITY IN WATER: 10 MG/ML  
SPECIFIC GRAVITY (WATER=1): Not applicable.  
VAPOR DENSITY (air = 1): Not applicable.  
VAPOR PRESSURE: Not applicable.  
VOLATILITY: Not applicable.

10. STABILITY AND REACTIVITY

STABILITY: Stable.  
PHYSICAL CONDITIONS TO AVOID: None.  
INCOMPATIBILITY WITH OTHER MATERIALS: None.  
HAZARDOUS DECOMPOSITION PRODUCTS: None.  
HAZARDOUS POLYMERIZATION: Will not occur.

11. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD: Incinerate or sanitary landfill.

12. SHIPPING REGULATIONS

Not regulated for transportation by the United States Department of Transportation (DOT). International Maritime Organization (IMO), or International Air Transport Association (IATA). May be subject to state and/or local transportation requirements.

13. OTHER INFORMATION

REVIEWED BY: Environmental Health Sciences.  
DISCLAIMER: The MSDS information is believed to be correct but should only be used as a guide. Pharmacia & Upjohn disclaims any express or implied warranty as to the accuracy of the MSDS information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the information.

14. LABELING

UPJOHN PRECAUTIONARY LABEL CODE(S): Q  
HAZARD: CHRONIC HAZARD.  
SIGNAL WORD: DANGER!  
STATEMENT OF HAZARD/RISK PHRASE: Long-term or repeated exposure may cause adverse health effects.  
PRECAUTIONARY MEASURES: Do not get in eyes, on skin, on clothing. Avoid breathing dust, vapor, mist or gas. Keep container closed. Use with adequate ventilation. Wash thoroughly after handling.  
EEC (EUROPE) HAZARD CLASS: HARMFUL.  
EEC (EUROPE) STANDARD RISK PHRASE(S): R 20/22 Harmful by inhalation and if swallowed. R 33 Danger of cumulative effects.  
EEC (EUROPE) STANDARD SAFETY PHRASE(S): S 36/37/39 Wear suitable protective clothing, gloves and eye/face protection.  
EEC (EUROPE) HAZARD SYMBOL: St. Andrew's Cross.

Pharmacia & Upjohn

BETAMETHASONE VALERATE

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DISCLAIMER OF EXPRESSED AND IMPLIED WARRANTIES: although preparer and owner have taken reasonable care in the preparation of this document, we extend no warranties and make no representation as to the accuracy or completeness of the information contained herein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequences of its use. Each user should make a determination as to the suitability of the information for their particular purpose(s). A request has been made to the manufacturer to approve the contents of this material safety data sheet. Upon receipt of any changes a new MSDS will be made available.  
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COMPAS Code: 29300370



# Material Safety Data Sheet

12601 Twinbrook Parkway,  
Rockville, MD 20852 USA

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## CLOTRIMAZOLE

Catalog Number: 1141002

Revision Date:

November 1, 2007

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**Common Name:** Clotrimazole

**Manufacturer:** U. S. Pharmacopeia

**Responsible Party:** Reference Standards Technical Services

**Mailing Address:** 12601 Twinbrook Parkway, Rockville, MD 20852 USA

**Phone:** 301-816-8129

**Hours:** 8 a.m. to 5 p.m. EST Mon. - Fri.

**Product Use:** USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

### SECTION 2 - HAZARD INFORMATION

#### EMERGENCY OVERVIEW - Irritant.

**Adverse Effects:** Adverse effects may include abdominal cramping or pain, diarrhea, nausea or vomiting, drowsiness, disorientation, unpleasant mouth sensations, and skin rash or irritation. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** n/f

**Acute:** Eye, skin, gastrointestinal and/or respiratory tract irritation.

**Chronic:** Possible hypersensitization.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material.

**Cross Sensitivity:** Persons sensitive to imidazoles may be sensitive to this material also.

**Target Organs:** n/f

**For additional information on toxicity, see Section 11.**

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**Common Name:** Clotrimazole

**Formula:** C<sub>22</sub>H<sub>17</sub>ClN<sub>2</sub>

**Synonym:** n/f

# CLOTRIMAZOLE

Catalog Number: 1141002

Revision Date:

November 1, 2007

**Chemical Name:** 1H-Imidazole, 1-[(2-chlorophenyl)diphenylmethyl]-

**CAS:** 23593-75-1

**RTECS Number:** NI4377000

**Chemical Family:** Imidazole derivative

**Therapeutic Category:** Antifungal

**Composition:** Pure Material

## SECTION 4 - FIRST AID MEASURES

**Inhalation:** May cause irritation. Avoid inhalation. Remove to fresh air.

**Eye:** Causes irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.

**Skin:** Causes irritation and may cause allergic dermatitis. Avoid contact. Flush with copious quantities of soap and water. This material is not absorbed through the skin.

**Ingestion:** May cause irritation. Avoid ingestion. Flush out mouth with water. This material is poorly absorbed from the gastrointestinal tract. Effects have a duration of action up to 3 hours.

**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.

### Note to Physicians

**Overdose Treatment:** For current information about the treatment of overdose, consult a certified Regional Poison Control Center by calling the number listed in your local telephone directory.

## SECTION 5 - FIREFIGHTING MEASURES

**Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.

**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

## SECTION 7 - HANDLING AND STORAGE

**Handling:** As a general rule, when handling USP Reference Standards avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Wash thoroughly after handling.

**Storage:** Store in tight, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

**Engineering Controls:** Engineering controls such as exhaust ventilation are recommended.

**Respiratory Protection:** Use a NIOSH-approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

**Gloves:** Chemically compatible

**Eye Protection:** Safety glasses or goggles

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**CLOTRIMAZOLE**

Catalog Number: 1141002

Revision Date:

November 1, 2007

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**Protective Clothing:** Protect exposed skin.**Exposure Limits:** Industry: 100 micrograms/m<sup>3</sup>

<b>SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES</b>
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**Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.****Appearance and Odor:** White to pale yellow crystalline powder; odorless**Odor Threshold:** n/f**pH:** 6.0 - 8.0 (10% aqueous solution)**Melting Range:** 142 - 149° C (decomposes)**Boiling Point:** n/f**Flash Point:** n/f**Autoignition Temperature:** n/f**Evaporation Rate:** n/f**Upper Flammability Limit:** n/f**Lower Flammability Limit:** n/f**Vapor Pressure:** n/f**Vapor Density:** n/f**Specific Gravity:** n/f**Solubility in Water:** Practically insoluble**Fat Solubility:** n/f**Other Solubility:** Freely soluble in methanol, in acetone, in chloroform, and in alcohol; very soluble in polyethylene glycol 400; soluble in ethyl acetate and in dimethylformamide; slightly soluble in toluene and in benzene; sparingly soluble in ether**Partition Coefficient: n-octanol/water:** 4.1**Percent Volatile:** n/f**Reactivity in Water:** n/f**Explosive Properties:** n/f**Oxidizing Properties:** n/f**Formula:** C<sub>22</sub>H<sub>17</sub>ClN<sub>2</sub>**Molecular Weight:** 344.84

# CLOTRIMAZOLE

Catalog Number: 1141002

Revision Date:

November 1, 2007

## SECTION 10 - STABILITY AND REACTIVITY

**Conditions to Avoid:** Avoid exposure to light.

**Incompatibilities:** Strong oxidizing agents

**Decomposition Products:** When heated to decomposition material emits very toxic fumes of Cl- and NOx. Emits toxic fumes under fire conditions.

**Stable?** Yes      **Hazardous Polymerization?** No

## SECTION 11 - TOXICOLOGICAL PROPERTIES

**Oral Rat:** LD50: 708 mg/kg

**Oral Mouse:** LD50: 761 mg/kg

**Other Toxicity Data:** Oral Dog LD50: >2 grams/kg

**Irritancy Data:** Rabbit/skin: practically not irritating; Rabbit/eye: slight

**Corrosivity:** n/f

**Sensitization Data:** n/f

**Listed as a Carcinogen by:**      **NTP:** No      **IARC:** No      **OSHA:** No

**Other Carcinogenicity Data:** There was no evidence of carcinogenicity in an 18-month study in rats given oral clotrimazole.

**Mutagenicity Data:** Clotrimazole did not have a mutagenic affect on the chromosomes of the spermatophores of exposed Chinese hamsters.

**Reproductive and Developmental Effects:** In a Hungarian case-control surveillance study including 18,515 infants with birth defects (7.1% of whom were born to mothers who received clotrimazole during pregnancy) and 32,804 control, nonmalformed infants (7.7% of whom were born to clotrimazole exposed mothers), there was no association found between birth defects and the use of clotrimazole during pregnancy.

Clotrimazole did not cause and increased birth defects in the offspring of rats, mice, and rabbits administered oral doses up to 100, 200, and 180 mg/kg, respectively, during pregnancy.

There were no adverse effects on the duration of estrous cycle, fertility, or duration of pregnancy in a study of male and female rats administered oral clotrimazole at doses up to 50 mg/kg/day. Clotrimazole was embryotoxic, fetotoxic, and maternally toxic in rats at 100 mg/kg/day.

## SECTION 12 - ECOLOGICAL INFORMATION

**Ecological Information:** n/f

## SECTION 13 - DISPOSAL CONSIDERATIONS

**Disposal:** Dispose of waste in accordance with all applicable Federal, State and local laws.

## SECTION 14 - TRANSPORT INFORMATION

**Shipping Name:** n/f

**Class:** n/f

**UN Number:** n/f

**Packing Group:** n/f

**Additional Transport Information:** n/f

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**CLOTRIMAZOLE****Catalog Number:** 1141002**Revision Date:**November 1, 2007

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**SECTION 15 - REGULATORY INFORMATION****U.S. Regulatory Information:** n/f**International Regulatory Information:** EINECS # 245-764-8  
Hazard Code: Xn, N  
Risk Phrases; R22, R36/38, R51/53**SECTION 16 - OTHER INFORMATION****Revision:** 01-Nov-07**Previous Revision Date:** 04-Sep-02