

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078305979

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

078071120 078073823 078073864 078349207

**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).**

078073831 078073849

# MATERIAL SAFETY DATA SHEET

--  
**Vet-A-Mix,**  
**A Division of LLOYD, Inc.**  
Phone No. (712) 246-4000  
Page 1 of 2

**P.O. Box 130, Shenandoah, IA 51601-0130**

Derma-Form Liquid  
MSDS Date: 4 Oct 2002 (Original)  
6/27/06 (Revised)

**Product Name: Derma-Form Liquid**

## 1. INGREDIENTS: (% w/w), unless otherwise noted

| COMPONENT | CAS# | % | EXPOSURE LIMITS, ppm |                                |
|-----------|------|---|----------------------|--------------------------------|
|           |      |   | OSHA PEL             | ACGIH TLV (mg/m <sup>3</sup> ) |

----- Not Applicable -----

This document is prepared pursuant to the OSHA Hazard Communication Standard (29 CFR 1910.1200). Only those ingredients composing  $\geq 1\%$  ( $\geq 0.1\%$  for carcinogens or suspect carcinogens) of the formula (w/w) and which have hazards identified are listed.

## 2. PHYSICAL DATA:

APPEARANCE: Amber clear oil. Specific gravity = 0.925. Other physical data have not been determined.

## 3. FIRE AND EXPLOSION HAZARD DATA:

This has not been evaluated.

EXTINGUISHING MEDIA: Water fog, alcohol foam, CO<sub>2</sub>, dry chemical.

## 4. REACTIVITY DATA:

This has not been evaluated. The product is expected to be stable under normal storage conditions; avoid strong oxidizers.

## 5. ENVIRONMENTAL AND DISPOSAL INFORMATION:

ACTION TO TAKE FOR SPILLS/LEAKS: Cover with absorbent material, soak up and sweep up and dispose of in DOT-approved waste containers. Keep out of sewers, storm drains, surface waters and soil.

DISPOSAL METHOD: Dispose of contaminated product and materials used in cleaning up spills or leaks in a manner approved for this material. Consult appropriate federal, state and local regulatory agencies to ascertain proper disposal procedures.

## 6. HEALTH HAZARD DATA:

EYE: This product is not expected to irritate the eyes under normal conditions of use.

SKIN CONTACT: This product is not expected to irritate the skin under normal conditions of use.

INGESTION: This has not been evaluated.

INHALATION: Inhalation exposure under normal conditions of use is not likely to cause adverse effects. Should vegetable oil mist exist, respiratory protection should be worn; vegetable oil mists are classified as a respiratory "nuisance particulate" (no health effects) by ACGIH.

# MATERIAL SAFETY DATA SHEET

---

--

**Vet-A-Mix,**  
**A Division of LLOYD, Inc.**  
Phone No. (712) 246-4000  
Page 2 of 2

**P.O. Box 130, Shenandoah, IA 51601-0130**

Derma-Form Liquid  
MSDS Date: 4 Oct 2002 (Original)  
6/27/06 (Revised)

## 7. **FIRST AID:**

**EYES:** Immediately flush eyes with copious amounts of running water for 15 minutes.

**SKIN:** Wash with soap and water.

**INGESTION:** SEEK MEDICAL ATTENTION IMMEDIATELY. Treatment is by gastric lavage or emesis.

**INHALATION:** If a person has been exposed to excessive quantities of dust due to mishaps, move the person to fresh air. Give artificial respiration if not breathing.

Seek medical attention immediately if excessive exposure occurs.

## 8. **HANDLING PRECAUTIONS:**

There is no OSHA PEL or ACGIH TLV for this product. Under normal conditions of use, no special handling precautions are required in areas with adequate ventilation. However, under conditions of prolonged exposure in which quantities of dust are generated, mechanical ventilation, safety glasses with side shields, gloves and a NIOSH approved dust respirator are recommended.

**SPECIAL PRECAUTIONS TO BE TAKEN IN HANDLING AND STORAGE:** Exercise reasonable care and caution.

## **REGULATORY INFORMATION: (Not meant to be all-inclusive--selected regulations represented.)**

**NOTICE:** The information herein is presented in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied, is given. Regulatory requirements are subject to change and may differ from one location to another; it is the buyer's responsibility to ensure that its activities comply with federal, state or provincial, and local laws. The following specific information is made for the purpose of complying with numerous federal, state or provincial, and local laws and regulations. See MSDS for health and safety information.

**U.S. REGULATIONS: SARA HAZARD CATEGORY:** This product has been reviewed according to the federal EPA "Hazard Categories" promulgated under Sections 311 and 312 of the Superfund Amendment and Reauthorization Act of 1986 (SARA Title III) and is considered, under applicable definitions, to be exempt from reporting requirements. Nevertheless, potential reporters should check with their state emergency response commissions to determine if this product must be reported under applicable state requirements.



Merck & Co., Inc.  
One Merck Dr.  
Whitehouse Station, NJ 08889

## MATERIAL SAFETY DATA SHEET

*Merck Animal Health urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.*

### SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

|                             |  |
|-----------------------------|--|
| <b>MSDS NAME:</b>           | <b>OTOMAX</b>  |
| <b>SYNONYM(S):</b>          | Otomax<br>CGB ointment<br>Malotic ointment<br>Otomax ointment  |
| <b>MSDS NUMBER:</b>         | SP000063   |
| <b>EMERGENCY NUMBER(S):</b> | (908) 423-6000 (24/7/365) English Only<br>Emergencies - CHEMTREC:<br>(800) 424-9300 (Inside Continental USA)<br>(703) 527-3887 (Outside Continental USA) |
| <b>MERCK MSDS HELPLINE:</b> | (800) 770-8878 (US and Canada)<br>(908) 473-3371 (Worldwide)<br>Monday to Friday, 9am to 5pm (US Eastern Time)   |

## SECTION 2. HAZARDS IDENTIFICATION

### EMERGENCY OVERVIEW

Viscous suspension  
Light beige  
Oil odor  
May be absorbed through the skin.  
May be harmful if absorbed through skin or if swallowed.  
May cause dermal sensitization.  
May be a reproductive toxicant.  
May cause developmental effects.  
*Causes effects to:*  
skin  
endocrine system

*May cause effects to:*  
nervous system  
musculoskeletal system  
gastrointestinal tract  
immune system  
liver  
kidney  
reproductive system  
fetus

### POTENTIAL HEALTH EFFECTS:

The toxicological properties of the mixture(s) have not been fully characterized in humans or animals. However, there are data to describe the toxicological properties of the individual ingredients. The following summary is based upon available information about the individual ingredients of the mixture(s), or of the expected properties of the mixture(s). Only information about the ingredients that are expected to contribute significantly to the potential health hazard profile of the formulation(s) are presented.

Clotrimazole is a broad-spectrum anti-fungal agent used for the treatment of dermal infections. Clotrimazole is poorly absorbed by skin or mucous membranes in humans. Clinical effects reported following the application of clotrimazole, as a 1% cream, on the skin included stinging, itching, redness, swelling, blisters, burning, peeling, itching eruptions (urticaria), and general irritation of the skin. Clotrimazole may cause sensitization of the skin in sensitive individuals. Reversible liver effects have also occurred in patients following clotrimazole treatment.

Betamethasone is an anti-inflammatory corticosteroid used in the treatment of various disease states. As a class, corticosteroids are known to cause systemic effects such as reversible suppression of the hypothalamic-pituitary-adrenal (HPA) axis, increased blood sugar, sugar in the urine, impairment of glucose tolerance, and changes in general metabolism, bone metabolism, white blood cell counts, and some blood serum chemistry levels. The clinical relevance of these changes in healthy adults is unknown. Cushing's syndrome may occur from excessive exposure to corticosteroids. Use of aerosolized corticosteroid inhalers has caused nasal irritation or burning, occasional sneezing, runny or bloody nose. Rare instances of nasal ulceration, septum perforation and increased intraocular pressure have been reported following prolonged use of or overexposure to aerosolized corticosteroids. Prolonged use of systemic steroids is also known to be associated with the formation of cataracts and glaucoma. Corticosteroids may mask some signs of infection, and opportunistic infections may appear during their use due to effects on immune system. Persons with pre-existing skin conditions including dermatitis and acne, a history of asthma, or those with a history of taking systemic steroids are more susceptible to allergic reactions from exposure to steroids. Serious health effects including death have occurred in asthmatic patients during transfer from systemic corticosteroid to topical corticosteroid clinical use.

Reported occupational effects include allergic skin reactions such as dermatitis and rash.

The most common side effects in studies with betamethasone-containing topical preparations were local, including erythema, steroid-induced rosacea (redness, acne-like reaction on face), mild burning, itching, skin dryness and irritation. Betamethasone has been shown to decrease collagen synthesis in human skin following treatment with topical cream. Adverse reactions reported following injection of betamethasone include effects on fluid and electrolytes, musculoskeletal, gastrointestinal, dermatologic, neurological, endocrine, ophthalmic and metabolic parameters.

Corticosteroids are teratogenic in laboratory animals and may be considered teratogenic in non-human primates as well. Widespread clinical use of corticosteroids has resulted in very few reports of teratogenic activity in humans. There is no evidence of impaired fertility in humans treated with corticosteroids although hypo-adrenalism may occur in infants born to mothers receiving corticosteroids during pregnancy.

Ingestion of mineral oil may cause laxative effect, nausea, dehydration or lipid pneumonia. Long-term dermal exposure to mineral oil may cause dermatitis and oil acne.

**MSDS NAME:** OTOMAX

**MSDS NUMBER:** SP000063

Latest Revision Date: 20-Jan-2012

Page 2 of 8

## LISTED CARCINOGENS

| INGREDIENT  | CAS NUMBER | OSHA | IARC | NTP | ACGIH |
|-------------|------------|------|------|-----|-------|
| Mineral Oil | 8012-95-1  |      |      |     | A2    |

This product contains a highly refined grade of mineral oil which is not classified as a carcinogen by IARC or NTP.

### SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

**PRODUCT USE:** Veterinary product

**CHEMICAL FORMULA:** Mixture.

The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed. For additional information about carcinogenic ingredients see Section 2.

### CHEMICAL COMPOSITION

| INGREDIENT                        | CAS NUMBER | PERCENT |
|-----------------------------------|------------|---------|
| Betamethasone Valerate            | 2152-44-5  | 0.12    |
| Ethene Homopolymer (Polyethylene) | 9002-88-4  | 29.88   |
| Gentamicin Sulfate (Preservative) | 1405-41-0  | 0.5     |
| Clotrimazole                      | 23593-75-1 | 1       |
| Mineral Oil                       | 8012-95-1  | 65-75   |

**ADDITIONAL INFORMATION:** This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

### SECTION 4. FIRST AID MEASURES

**INHALATION:** Remove 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.

**SKIN CONTACT:** 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.

**EYE CONTACT:** In case of eye contact, immediately rinse eyes thoroughly with plenty of water. 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.

**INGESTION:** Rinse mouth and drink a glass of water. Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. If symptoms persist, consult a physician.

**NOTE TO PHYSICIAN:** This product contains clotrimazole, a broad spectrum antifungal agent, and betamethasone dipropionate, 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.

### SECTION 5. FIRE FIGHTING MEASURES

**FLAMMABILITY DATA:**

Flash Point: Not determined (liquids) or not applicable (solids).

**SPECIAL FIRE FIGHTING PROCEDURES:**

Wear full protective clothing and self-contained breathing apparatus (SCBA).

**SUITABLE EXTINGUISHING MEDIA:**

Carbon dioxide (CO<sub>2</sub>), extinguishing powder or water spray.

**MSDS NAME:** OTOMAX

**MSDS NUMBER:** SP000063

Latest Revision Date: 20-Jan-2012

Page 3 of 8

## SECTION 5. FIRE FIGHTING MEASURES

See Section 9 for Physical and Chemical Properties.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

### PERSONAL PRECAUTIONS:

Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

### SPILL RESPONSE / CLEANUP:

All spills should be handled according to site requirements and based on precautions cited in the MSDS. 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 HEPA filtered 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, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

## SECTION 7. HANDLING AND STORAGE

### HANDLING:

Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

### STORAGE:

Store in a cool, dry, well ventilated area.

See Section 8 for exposure controls and additional safe handling information.

## SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation.

### OCCUPATIONAL EXPOSURE BAND (OEB):

OEB 4: 1-10 mcg/m<sup>3</sup>. Materials in an OEB 4 category are considered high health hazards. The OEB is range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

### OCCUPATIONAL EXPOSURE GUIDELINE (OEG):

An Occupational Exposure Guideline of 5 mcg/m<sup>3</sup> (8-hr TWA) has been established for betamethasone (base).

### OEB/OEL NOTATION(S):

Betamethasone: This material has a notation of "S" for its ability to cause systemic toxicity through skin absorption.

### EXPOSURE CONTROLS

The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

### RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):

#### Respiratory Protection:

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. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance.

#### Skin Protection:

Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance.

MSDS NAME: OTOMAX

MSDS NUMBER: SP000063

Latest Revision Date: 20-Jan-2012

Page 4 of 8

Eye Protection: Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance.

Body Protection: 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.

In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on 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.

### EXPOSURE LIMIT VALUES

| INGREDIENT  | CAS NUMBER | ACGIH TLV (TWA)     | OSHA PEL (TWA)      |
|-------------|------------|---------------------|---------------------|
| Mineral Oil | 8012-95-1  | 5 mg/m <sup>3</sup> | 5 mg/m <sup>3</sup> |

Fields in the above table(s) that do not contain data indicate that exposure limits are not available for those endpoints.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**FORM:** Viscous suspension  
**COLOR:** Light beige  
**ODOR:** Oil odor  
**SOLUBILITY:**  
 Water: Not determined

See Section 5 for flammability/explosivity information.

### SECTION 10. STABILITY AND REACTIVITY

**STABILITY/ REACTIVITY:**  
 Stable under normal conditions.

**INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:**  
 Open flames and high temperatures. Oxidizers. Strong acids and bases.

**HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:**  
 Carbon oxides (COx).

### SECTION 12. ECOLOGICAL INFORMATION

#### ECOTOXICITY DATA

There are no ecotoxicity data available for these products or their components.

#### ENVIRONMENTAL DATA

There are no environmental data available for this product or its components.

### SECTION 11. TOXICOLOGICAL INFORMATION

The toxicological properties of this material have not been fully characterized in humans or animals. The information presented below pertains to the following individual ingredients in this formulation, unless indicated otherwise.

#### ACUTE TOXICITY DATA



**INHALATION:**

Rats dosed with clotrimazole at 0.73 mg/L (maximum attainable level) for 4 hours exhibited lacrimation, salivation, nasal discharge, ano-genital staining, stool changes, and dried black material on extremities. Significant weight loss was observed the day after exposure and continued for a week after treatment. One animal died six days after exposure. All other animals appeared normal by the end of the observation period. At necropsy, discolored liver, nasal turbinates, and dilated renal pelvis were noted; however, it was unclear if these were treatment related effects.

In an acute inhalation toxicity study in rats at 0.59 mg/l betamethasone dipropionate (maximum attainable concentration), animals exhibited labored breathing, eye closure and decreased activity during exposure. All animals recovered within one day after exposure.

Rats and mice were exposed by inhalation to an aerosol containing 0.3 mg of betamethasone dipropionate per liter over a 5-hour period. Both species exhibited body weight decreases during the 4 day post treatment period. During exposure the mice exhibited transient central nervous system stimulation including excitation, tremors and convulsions. Recovery was prompt. Upon microscopic examination, partial thymic involution was seen in both species. This finding together with the loss in body weight was attributed to the known pharmacological activity of a corticosteroid.

Ethene homopolymer: Practically not toxic.

**SKIN:**

Clotrimazole was practically not irritating to rabbit skin.

Betamethasone produced erythema which was present five hours after dosing in a skin irritation study in rabbits but resolved by 96 hours after dosing. There were no adverse skin changes detected in dermal toxicity studies of betamethasone dipropionate cream (0.05% or 0.1%) in hairless mice, rats, rabbits or dogs.

Mineral oil was slightly irritating to the skin of rabbits.

**EYE:**

OTOMAX is minimally irritating to the eyes of rabbits.

**ORAL:**

Clotrimazole: Oral LD50: 708 mg/kg (rat); 761-923 mg/kg (mouse); >1000 mg/kg (rabbit); >1000 mg/kg (dog)

Betamethasone dipropionate: Oral LD50: >1000 mg/kg (dog); >5000 mg/kg (rat); >50 mg/kg (mice)

One male and one female dog were each administered a single oral dose of 1000 mg/kg of betamethasone dipropionate and observed for five weeks. Urine output and water consumption were increased and eosinophil counts decreased during the week post treatment.

Ethene homopolymer: Practically not toxic.

Mineral Oil: Oral LD50: 22,000 mg/kg (mouse)

**DERMAL AND RESPIRATORY SENSITIZATION:**

A betamethasone dipropionate (0.05%) ointment formulation was determined to be a potentially weak sensitizer in guinea pigs. Local irritation at the intradermal injection sites was observed during the induction phase.

Mineral oil was not a skin sensitizer in guinea pigs.

**REPEAT DOSE TOXICITY DATA**

**SUBCHRONIC / CHRONIC TOXICITY:**

Clotrimazole was fed to rats at doses of 10, 25, 50, or 150 mg/kg/day in the diet for 18 months. The only clinical effect observed during the study was decreased body weight in the 50 (females) and 150 mg/kg/day dosage groups; however, reversal of body weight loss was noted in rats not dosed during the last 25 weeks of the study. Chemical and pathological effects observed during the study included decreases in hematocrit and hemoglobin values (50 and 150 mg/kg/day), increases in serum chemistry levels (150 mg/kg/day males), dose- and treatment-related incidences of liver mottling, nodular enlargement, pigmentation of the renal cortices, fatty metamorphosis and regenerative hyperplasia of the liver, and deposits of intracellular fat in the adrenal glands. Reversal of liver effects were observed in rats not dosed during the last 25 weeks of the study. A NOEL was not determined for this study.

Dogs were treated with clotrimazole at doses of 25, 50, or 150 mg/kg/day for six or twelve months. Dose-related clinical effects observed included emesis shortly after dosing, soft stool, transient increased salivation, conjunctivitis accompanied by lacrimation, and body weight loss (high-dose group). Most effects were not observed during the recovery period. Chemical and pathological effects were observed in the mid- or high-dose groups and included increases in serum chemistry levels (similar to those seen in rats) and increased fat deposits in the adrenal glands. A NOEL was not determined for this study.

Rabbits are the most sensitive species tested with betamethasone dipropionate in regards to repeated topical skin application. Serious effects including death, hypothalamic-pituitary-adrenal (HPA) axis suppression, skeletal muscle wasting, immune organ atrophy, and abdominal distention in more than 50% of animals tested were observed following application for 10 to 30 days with 0.05% betamethasone propionate cream, lotion or ointment formulations. However, rats and mice demonstrated only minimal systemic effects, principally thymic involution, when either 0.05% or 0.1% cream was applied to skin six days a week for up to eight weeks.

In a 14-day oral toxicity study testing the 0.1% betamethasone topical cream formulation in rats and mice, drug-related clinical signs including diarrhea, hypothermia and rough coat, were observed within three hours to six days after dosing. Hypoactivity and ptosis were also seen in rats. In a 28-day oral toxicity study in dogs treated with 0.05 to 1 mg/kg/day of betamethasone dipropionate, drug-related effects observed included reversible changes in hematological, biochemical and physiological data (increased fluid intake and urinary output, decreased hematocrit and hemoglobin values, alterations in white blood cell counts, increases in liver enzymes, thymic involution and adrenal atrophy) which were attributed to the known pharmacological activity of corticosteroid drugs.

Female rats received mineral oil in the diet at dosages up to 20,000 ppm for 90 days. Effects observed included increased liver, kidney, and spleen weights, and enlargement of the lymph nodes together with granulomatous lipid granules.

**REPRODUCTIVE / DEVELOPMENTAL TOXICITY:**

High oral doses of clotrimazole in rats and mice ranging from 50 to 120 mg/kg resulted in embryotoxicity (possibly secondary to maternal toxicity), impairment of mating, decreased litter size and number of viable young, and decreased pup survival to weaning. Clotrimazole was not teratogenic in rats, rabbits, or mice given oral doses up to 100, 180, or 200 mg/kg, respectively. Intravaginal dosing of 100 mg/kg in pregnant rats did not result in harm to the fetuses.

Corticosteroids are known teratogens in rodent species with some teratogenic effects having been observed in non-human primates. They are generally teratogenic in laboratory animals when administered systemically at low dosages.

Subcutaneous administration of up to 0.42 mg of a mixture of betamethasone/sodium phosphate and betamethasone/acetate suspension, on days 12 and 13 of gestation in pregnant rats, caused decreases in maternal and fetal weight gain, occurrence of cleft palate and omphalocele (umbilical hernia), and impaired growth of fetal heart, liver, adrenals, kidneys, and skeletal muscle. Dose-related increases in fetal resorptions in rabbits and mice following single intramuscular doses up to 1 and 33 mg/kg, respectively were observed. Additionally, betamethasone dipropionate has been shown to produce umbilical hernias, cephalocele (cranial protrusion) and cleft palate in rabbits when given intramuscular doses of 0.05 mg/kg/day during gestation. Suppression of adrenocorticotrophic hormone (ACTH), following intramuscular administration of betamethasone in monkeys during gestation resulted in decreases in fetal adrenal weight, cortical cell size, appearance of apoptosis and cellular disorganization.

**MUTAGENICITY / GENOTOXICITY:**

Clotrimazole (100 mg/kg/day) was negative in a chromosome spermatophore study in Chinese hamsters.

Betamethasone was negative in a bacterial mutagenicity study (Ames) and mammalian cell mutagenicity assay (CHO/HGPRT) and positive in the in vitro human lymphocyte chromosome aberration assay. Equivocal results were seen in the in vivo mouse bone marrow micronucleus assay.

**CARCINOGENICITY:**

Clotrimazole was not carcinogenic in rats exposed to oral doses for 18 months.

There was no evidence of carcinogenicity in animals exposed to mineral oil mist at 100 mg/m<sup>3</sup> or higher for as long as two years.

|  |
|--|
| <b>SECTION 13. DISPOSAL CONSIDERATIONS</b> |
|--|

**MATERIAL WASTE:**

Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

**PACKAGING AND CONTAINERS:**

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

**SECTION 14. TRANSPORT INFORMATION**

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

**SECTION 15. REGULATORY INFORMATION****TSCA LISTING**

| INGREDIENT                        | TSCA |
|-----------------------------------|------|
| Ethene Homopolymer (Polyethylene) | X    |
| Mineral Oil                       | X    |

Substances not included in the table above are TSCA exempt or not regulated under TSCA.

**U.S. STATE REGULATIONS**

| INGREDIENT  | California Proposition 65 | CARTK | NJRTK | CTR TK | MARTK |
|-------------|---------------------------|-------|-------|--------|-------|
| Mineral Oil |                           | X     | 1437  |        | X     |

| INGREDIENT  | PARTK | MNRTK | MIRTK | RIRTK |
|-------------|-------|-------|-------|-------|
| Mineral Oil | X     | X     |       | X     |

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations.

X: Listed on applicable state hazardous substance or right-to-know lists.

**SECTION 16. OTHER INFORMATION**

Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

**DEPARTMENT ISSUING MSDS:**

Global Safety & the Environment  
Merck & Co., Inc.  
One Merck Drive  
Whitehouse Station, NJ 08889

**MERCK MSDS HELPLINE:**

(800) 770-8878 (US and Canada)  
(908) 473-3371 (Worldwide)  
Monday to Friday, 9am to 5pm (US Eastern Time)

**MSDS CREATION DATE:**

01-Dec-1999

**SUPERSEDES DATE:**

25-Mar-2010

**SECTIONS CHANGED (US SUBFORMAT):  
SIGNIFICANT CHANGES (US SUBFORMAT):**

Complete rewrite  
Conversion, OEG, OEB

MSDS NAME: OTOMAX

MSDS NUMBER: SP000063

Latest Revision Date: 20-Jan-2012

Page 8 of 8

# SAFETY DATA SHEET

DERMA-FORM LIQUID

Revision 01

Revision Date: 23 July 2015

## 1. IDENTIFICATION

**Product Name:** Derma-Form Liquid

**Synonyms:** Vitamin Supplement

**Company:** **LLOYD, Inc.**  
604 West Thomas Avenue  
P.O. Box 130  
Shenandoah, IA 51601-0130  
USA  
(712) 246-4000

**Emergency Contact:** National Capital Poison Center  
(800) 222-1222

**Recommended Use:** To maintain healthy skin and hair coat by providing polyunsaturated fatty acids and vitamins A, D and E in the diet of dogs and cats.

## 2. HAZARDS IDENTIFICATION

### WARNING



**EYE:** This product is not expected to irritate the eyes under normal conditions of use.

**SKIN CONTACT:** This product is not expected to irritate the skin under normal conditions of use.

**INGESTION:** This has not been evaluated.

**INHALATION:** Inhalation exposure under normal conditions of use is not likely to cause adverse effects. Should vegetable oil mist exist, respiratory protection should be worn; vegetable oil mists are classified as a respiratory "nuisance particulate" (no health effects) by ACGIH.

## 3. INFORMATION ON INGREDIENTS

(% w/w), unless otherwise noted

| COMPONENT                      | CAS# | % | EXPOSURE LIMITS, ppm |                                   |
|--------------------------------|------|---|----------------------|-----------------------------------|
|                                |      |   | OSHA<br>PEL          | ACGIH<br>TLV (mg/m <sup>3</sup> ) |
| - - - - Not Applicable - - - - |      |   |                      |                                   |

This document is prepared pursuant to the OSHA Hazard Communication Standard (29 CFR 1910.1200). Only those ingredients composing  $\geq 1\%$  ( $\geq 0.1\%$  for carcinogens or suspect carcinogens) of the formula (w/w) and which have hazards identified are listed.

**4. FIRST AID MEASURES**

**EYES:** Immediately flush eyes with copious amounts of running water for 15 minutes.

**SKIN:** Wash with soap and water.

**INGESTION: SEEK MEDICAL ATTENTION IMMEDIATELY.** Treatment is by gastric lavage or emesis.

**INHALATION:** If a person has been exposed to excessive quantities of dust due to mishaps, move the person to fresh air. Give artificial respiration if not breathing.

**SEEK MEDICAL ATTENTION IMMEDIATELY IF EXCESSIVE EXPOSURE OCCURS.**

---

**5. FIREFIGHTING MEASURES**

This has not been evaluated.

**Extinguishing media:** Water fog, alcohol foam, CO<sub>2</sub>, dry chemical.

---

**6. ACCIDENTAL RELEASE MEASURES**

**Action to take for spills/leaks:** Sweep up and dispose of in DOT-approved waste containers. Keep out of sewers, storm drains, surface waters and soil.

---

**7. HANDLING AND STORAGE**

**Special precautions to be taken in handling and storage:** Exercise reasonable care and caution.

---

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

There is no OSHA PEL or ACGIH TLV for this product. Under normal conditions of use, no special handling precautions are required in areas with adequate ventilation. However, under conditions of prolonged exposure in which quantities of dust are generated, mechanical ventilation, safety glasses with side shields, gloves and a NIOSH approved dust respirator are recommended.

---

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance:** Amber clear oil. Specific gravity = 0.925.

Other physical data have not been determined.

---

**10. STABILITY AND REACTIVITY**

This has not been evaluated. The product is expected to be stable under normal storage conditions; avoid strong oxidizers.

---

**11. TOXICOLOGICAL INFORMATION**

N/A

---

**12. ECOLOGICAL INFORMATION**

**Action to take for spills/leaks:** Sweep up and dispose of in DOT-approved waste containers. Keep out of sewers, storm drains, surface waters and soil.

---

**13. DISPOSAL CONSIDERATIONS**

Dispose of contaminated product and materials used in cleaning up spills or leaks in a manner approved for this material. Consult appropriate federal, state and local regulatory agencies to ascertain proper disposal procedures.

---

**14. TRANSPORT INFORMATION**

No special transportation required

---

**15. REGULATORY INFORMATION**

**(Not meant to be all-inclusive--selected regulations represented.)**

NOTICE: The information herein is presented in good faith and believed to be accurate as of the effective date shown above. However, no warranty, express or implied, is given. Regulatory requirements are subject to change and may differ from one location to another; it is the buyer's responsibility to ensure that its activities comply with federal, state or provincial, and local laws. The following specific information is made for the purpose of complying with numerous federal, state or provincial, and local laws and regulations. See SDS for health and safety information.

**U.S. REGULATIONS:** SARA HAZARD CATEGORY: This product has been reviewed according to the federal EPA "Hazard Categories" promulgated under Sections 311 and 312 of the Superfund Amendment and Reauthorization Act of 1986 (SARA Title III) and is considered, under applicable definitions, to be exempt from reporting requirements. Nevertheless, potential reporters should check with their state emergency response commissions to determine if this product must be reported under applicable state requirements.

---

**16. OTHER INFORMATION**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**Clotrimazole / Gentamicin / Betamethasone  
(0.1%) Formulation**

Version 3.1      Revision Date: 04/12/2018      SDS Number: 808853-00009      Date of last issue: 10/10/2017  
Date of first issue: 07/22/2016

---

**SECTION 1. IDENTIFICATION**

Product name : Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

**Manufacturer or supplier's details**

Company name of supplier : Merck & Co., Inc  
Address : 2000 Galloping Hill Road  
Kenilworth - New Jersey - U.S.A. 07033  
Telephone : 908-740-4000  
Telefax : 908-735-1496  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product

---

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Reproductive toxicity : Category 1A  
Specific target organ systemic toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus, Blood, Adrenal gland)  
Specific target organ systemic toxicity - repeated exposure (Oral) : Category 2 (Liver, Kidney, Adrenal gland)

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H360Df May damage the unborn child. Suspected of damaging fertility.  
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus, Blood, Adrenal gland) through prolonged or repeated exposure.  
H373 May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

---

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 3.1      Revision Date: 04/12/2018      SDS Number: 808853-00009      Date of last issue: 10/10/2017  
Date of first issue: 07/22/2016

Precautionary Statements : **Prevention:**  
 P201 Obtain special instructions before use.  
 P202 Do not handle until all safety precautions have been read and understood.  
 P260 Do not breathe mist or vapors.  
 P264 Wash skin thoroughly after handling.  
 P270 Do not eat, drink or smoke when using this product.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.

**Storage:**  
 P405 Store locked up.

**Disposal:**  
 P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Hazardous ingredients

| Chemical name                 | CAS-No.    | Concentration (% w/w) |
|-------------------------------|------------|-----------------------|
| White mineral oil (petroleum) | 8042-47-5  | >= 90 - <= 100        |
| Clotrimazole                  | 23593-75-1 | >= 1 - < 5            |
| Gentamicin                    | 1403-66-3  | >= 0.1 - < 1          |
| Betamethasone                 | 378-44-9   | >= 0.1 - < 1          |

### SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately., When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.



## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

- |   |   |   |
|---|---|---|
| In case of eye contact                                      | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.  |
| If swallowed  | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |
| Most important symptoms and effects, both acute and delayed | : | May damage the unborn child. Suspected of damaging fertility.<br>Causes damage to organs through prolonged or repeated exposure.                            |
| Protection of first-aiders                                  | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists. |
| Notes to physician  | : | Treat symptomatically and supportively.   |
- 

### SECTION 5. FIRE-FIGHTING MEASURES

- |  |   |   |
|--|---|---|
| Suitable extinguishing media                   | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical  |
| Unsuitable extinguishing media                 | : | None known.   |
| Specific hazards during fire fighting          | : | Exposure to combustion products may be a hazard to health.  |
| Hazardous combustion products                  | : | Carbon oxides   |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |
- 

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |   |   |  |
|---|---|--|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice and personal protective equipment recommendations. |
| Environmental precautions   | : | Discharge into the environment must be avoided.<br>Prevent further leakage or spillage if safe to do so.             |

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

Prevent spreading over a wide area (e.g., by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

---

### SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe vapors or spray mist.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
Gases

---

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 3.1      Revision Date: 04/12/2018      SDS Number: 808853-00009      Date of last issue: 10/10/2017  
Date of first issue: 07/22/2016

| Components                    | CAS-No.    | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis     |
|-------------------------------|------------|----------------------------------|--|-----------|
| White mineral oil (petroleum) | 8042-47-5  | TWA (Mist)                       | 5 mg/m <sup>3</sup>                            | OSHA Z-1  |
|                               |            | TWA (Inhalable fraction)         | 5 mg/m <sup>3</sup>                            | ACGIH     |
|                               |            | TWA (Mist)                       | 5 mg/m <sup>3</sup>                            | NIOSH REL |
|                               |            | ST (Mist)                        | 10 mg/m <sup>3</sup>                           | NIOSH REL |
| Clotrimazole                  | 23593-75-1 | TWA                              | 0.2 mg/m <sup>3</sup> (OEB 2)                  | Internal  |
| Gentamicin                    | 1403-66-3  | TWA                              | 0.1 mg/m <sup>3</sup> (OEB 2)                  | Internal  |
| Betamethasone                 | 378-44-9   | TWA                              | 1 µg/m <sup>3</sup> (OEB 4)                    | Internal  |
| Further information: Skin     |            |                                  |  |           |
|                               |            | Wipe limit                       | 10 µg/100 cm <sup>2</sup>                      | Internal  |

**Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

### Personal protective equipment

**Respiratory protection** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### Hand protection

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

**Eye protection** : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

aerosols.

- Skin and body protection : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

---

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid
- Color : No data available
- Odor : No information available.
- Odor Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : No data available
- Evaporation rate : No data available
- Flammability (solid, gas) : Not applicable
- Flammability (liquids) : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapor pressure : No data available
- Relative vapor density : No data available

# SAFETY DATA SHEET



## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

|  |   |  |
|--|---|--|
| Relative density                           | : | No data available  |
| Density                                    | : | No data available  |
| Solubility(ies)<br>Water solubility        | : | No data available  |
| Partition coefficient: n-<br>octanol/water | : | Not applicable   |
| Autoignition temperature                   | : | No data available  |
| Decomposition temperature                  | : | No data available  |
| Viscosity<br>Viscosity, kinematic          | : | No data available  |
| Explosive properties                       | : | Not explosive  |
| Oxidizing properties                       | : | The substance or mixture is not classified as oxidizing. |
| Particle size                              | : | Not applicable   |

---

### SECTION 10. STABILITY AND REACTIVITY

|   |   |  |
|---|---|--|
| Reactivity                              | : | Not classified as a reactivity hazard.         |
| Chemical stability                      | : | Stable under normal conditions.                |
| Possibility of hazardous reac-<br>tions | : | Can react with strong oxidizing agents.        |
| Conditions to avoid                     | : | None known.                                    |
| Incompatible materials                  | : | Oxidizing agents                               |
| Hazardous decomposition<br>products     | : | No hazardous decomposition products are known. |

---

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 200 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

### Components:

#### **White mineral oil (petroleum):**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

#### **Clotrimazole:**

Acute oral toxicity : LD50 (Rat): 708 mg/kg  
LD50 (Mouse): 761 mg/kg  
LD50 (Rabbit): > 1,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.73 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Mouse): 923 mg/kg

#### **Gentamicin:**

Acute oral toxicity : LD50 (Rat): 8,000 - 10,000 mg/kg  
LD50 (Mouse): 10,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg  
Application Route: Intravenous

**Clotrimazole / Gentamicin / Betamethasone  
(0.1%) Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

LD50 (Rat): 371 - 384 mg/kg  
Application Route: Intramuscular

LDLo (Monkey): 30 mg/kg  
Application Route: Intravenous

**Betamethasone:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): > 4,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0.4 mg/l  
Exposure time: 4 h

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****White mineral oil (petroleum):**

Species : Rabbit  
Result : No skin irritation

**Clotrimazole:**

Species : Rabbit  
Result : No skin irritation

**Gentamicin:**

Species : Rabbit  
Result : Mild skin irritant

**Betamethasone:**

Species : Rabbit  
Result : Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****White mineral oil (petroleum):**

Species : Rabbit  
Result : No eye irritation

**Clotrimazole:**

Species : Rabbit  
Result : Mild eye irritation

**Clotrimazole / Gentamicin / Betamethasone  
(0.1%) Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

**Gentamicin:**

Species : Rabbit  
Result : Mild eye irritant

**Betamethasone:**

Species : Rabbit  
Result : No eye irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****White mineral oil (petroleum):**

Test Type : Buehler Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

**Gentamicin:**

Remarks : No data available

**Betamethasone:**

Routes of exposure : Dermal  
Species : Guinea pig  
Result : Weak sensitizer

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****White mineral oil (petroleum):**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

**Clotrimazole:**



## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
- Test Type: Chromosome aberration test in vitro  
Result: negative
- Test Type: in vitro micronucleus test  
Result: negative
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cyto-genetic assay)  
Species: Rat  
Application Route: Oral  
Result: negative
- Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)  
Species: Hamster  
Result: negative
- Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### **Gentamicin:**

- Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative
- Test Type: Chromosome aberration test in vitro  
Result: equivocal
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cyto-genetic assay)  
Species: Mouse  
Application Route: Intravenous injection  
Result: negative

### **Betamethasone:**

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative
- Test Type: In vitro mammalian cell gene mutation test  
Result: negative
- Test Type: Chromosome aberration test in vitro  
Result: positive
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cyto-genetic assay)  
Species: Mouse  
Application Route: Oral  
Result: equivocal

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity

Not classified based on available information.

### Components:

#### White mineral oil (petroleum):

Species : Rat  
 Application Route : Ingestion  
 Exposure time : 24 Months  
 Result : negative

#### Clotrimazole:

Species : Rat  
 Application Route : Oral  
 Exposure time : 78 weeks  
 Result : negative

#### Gentamicin:

Carcinogenicity - Assessment : No data available

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

### Components:

#### White mineral oil (petroleum):

Effects on fertility : Test Type: One-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Skin contact  
 Result: negative

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

#### Clotrimazole:

Effects on fertility : Test Type: Fertility/early embryonic development

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

Species: Rat  
 Application Route: Oral  
 Fertility: LOAEL: 50 mg/kg body weight  
 Result: Effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: LOAEL: 100 mg/kg body weight  
 Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 50 mg/kg body weight  
 Result: Embryo-fetal toxicity., No teratogenic effects.

Test Type: Embryo-fetal development  
 Species: Mouse  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 200 mg/kg body weight  
 Result: No effects on fetal development.

Test Type: Embryo-fetal development  
 Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 180 mg/kg body weight  
 Result: No effects on fetal development.

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

### Gentamicin:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
 Species: Rat  
 Fertility: NOAEL: 20 mg/kg body weight  
 Result: No significant adverse effects were reported

Effects on fetal development : Test Type: Embryo-fetal development  
 Species: Rabbit  
 Developmental Toxicity: NOAEL: 3.6 mg/kg body weight  
 Result: No embryo-fetal toxicity.

Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Intraperitoneal  
 Developmental Toxicity: LOAEL: 75 mg/kg body weight  
 Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development  
 Species: Mouse

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

Application Route: Intraperitoneal  
 Developmental Toxicity: LOAEL: 10 mg/kg body weight  
 Result: Fetal mortality., No malformations were observed.

Test Type: Embryo-fetal development  
 Species: Rat  
 Application Route: Intraperitoneal  
 Developmental Toxicity: LOAEL: 50 mg/kg body weight  
 Result: Fetal mortality., No malformations were observed.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

### **Betamethasone:**

Effects on fetal development : Species: Rabbit  
 Application Route: Intramuscular  
 Developmental Toxicity: LOAEL: 0.05 mg/kg body weight  
 Result: Fetotoxicity., Malformations were observed.

Species: Rat  
 Application Route: Subcutaneous  
 Developmental Toxicity: LOAEL: 0.42 mg/kg body weight  
 Result: Malformations were observed.

Species: Mouse  
 Application Route: Intramuscular  
 Developmental Toxicity: LOAEL: 1 mg/kg body weight  
 Result: Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

### **STOT-single exposure**

Not classified based on available information.

### **STOT-repeated exposure**

Causes damage to organs (Pituitary gland, Immune system, muscle, thymus, Blood, Adrenal gland) through prolonged or repeated exposure.  
 May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

### **Components:**

#### **Clotrimazole:**

Target Organs : Liver, Kidney, Adrenal gland  
 Assessment : May cause damage to organs through prolonged or repeated exposure.

#### **Gentamicin:**

Target Organs : Kidney, inner ear  
 Assessment : Causes damage to organs through prolonged or repeated exposure.

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

**Betamethasone:**

Target Organs : Pituitary gland, Immune system, muscle, thymus, Blood, Adrenal gland

Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****White mineral oil (petroleum):**

Species : Rat

LOAEL : 160 mg/kg

Application Route : Ingestion

Exposure time : 90 Days

Species : Rat

LOAEL :  $\geq 1$  mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 4 Weeks

Method : OECD Test Guideline 412

**Clotrimazole:**

Species : Rabbit

LOAEL : 5 - 40 mg/kg

Application Route : Skin contact

Exposure time : 3 Weeks

Target Organs : Skin

Symptoms : Edema, Fissuring, Necrosis, Redness

Species : Rat

LOAEL : 10 mg/kg

Application Route : Oral

Exposure time : 18 Months

Target Organs : Liver, Kidney, Adrenal gland

Species : Dog

LOAEL : 25 mg/kg

Application Route : Oral

Exposure time : 6 - 12 Months

Target Organs : Adrenal gland

Symptoms : Salivation, Lachrymation, Vomiting

**Gentamicin:**

Species : Dog

LOAEL : 3 mg/kg

Application Route : Intramuscular

Exposure time : 12 Months

Target Organs : Kidney

Symptoms : Vomiting, Salivation

**Clotrimazole / Gentamicin / Betamethasone  
(0.1%) Formulation**

Version 3.1      Revision Date: 04/12/2018      SDS Number: 808853-00009      Date of last issue: 10/10/2017  
Date of first issue: 07/22/2016

---

Species : Monkey  
LOAEL : 50 mg/kg  
Application Route : Subcutaneous  
Exposure time : 3 Weeks  
Target Organs : Kidney, inner ear

Species : Monkey  
LOAEL : 6 mg/kg  
Application Route : Intramuscular  
Exposure time : 3 Weeks  
Target Organs : Blood, Kidney, inner ear, Liver

Species : Rat  
NOAEL : 5 mg/kg  
LOAEL : 10 mg/kg  
Application Route : Intramuscular  
Exposure time : 52 Weeks  
Target Organs : Kidney, Blood

Species : Rat  
NOAEL : 12.5 mg/kg  
LOAEL : 50 mg/kg  
Application Route : Intramuscular  
Exposure time : 13 Weeks  
Target Organs : Kidney

**Betamethasone:**

Species : Rabbit  
LOAEL : 0.05 %  
Application Route : Skin contact  
Exposure time : 10 - 30 d  
Target Organs : Pituitary gland, Immune system, muscle

Species : Rat  
LOAEL : 0.05 %  
Application Route : Skin contact  
Exposure time : 8 Weeks  
Target Organs : thymus

Species : Mouse  
LOAEL : 0.1 %  
Application Route : Skin contact  
Exposure time : 8 Weeks  
Target Organs : thymus

Species : Dog  
LOAEL : 0.05 mg/kg  
Application Route : Oral  
Exposure time : 28 d  
Target Organs : Blood, thymus, Adrenal gland

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **Clotrimazole:**

Skin contact : Symptoms: Rash, Itching, Blistering, Edema, Redness

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea

#### **Gentamicin:**

Ingestion : Target Organs: Kidney

Target Organs: inner ear  
Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

#### **Betamethasone:**

Inhalation : Target Organs: Adrenal gland

Skin contact : Symptoms: Redness, pruritis, Irritation

---

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **White mineral oil (petroleum):**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae : NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l  
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1,000 mg/l  
Exposure time: 21 d

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

### Clotrimazole:

- Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 0.29 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.02 mg/l  
Exposure time: 48 h
- Toxicity to algae : EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l  
Exposure time: 72 h
- NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l  
Exposure time: 72 h
- Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.01 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211
- Toxicity to microorganisms : EC50: > 10,000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Gentamicin:

- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 86 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- LC50 (Americamysis): 30 mg/l  
Exposure time: 96 h  
Method: US-EPA OPPTS 850.1035
- Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201
- NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201



**Clotrimazole / Gentamicin / Betamethasone  
(0.1%) Formulation**

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

Toxicity to microorganisms : EC50: 288.7 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

**Betamethasone:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Americamysis): > 50 mg/l  
Exposure time: 96 h

Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l  
Exposure time: 32 d  
Method: OECD Test Guideline 210

NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l  
Exposure time: 219 d  
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 8 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

**Persistence and degradability****Components:****White mineral oil (petroleum):**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 31 %  
Exposure time: 28 d

**Clotrimazole:**

Stability in water : Hydrolysis: 50 %(242 d)

**Gentamicin:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 100 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

### Bioaccumulative potential

#### Components:

##### Gentamicin:

Partition coefficient: n-octanol/water : log Pow: < -2

##### Betamethasone:

Partition coefficient: n-octanol/water : log Pow: 2.11

#### Mobility in soil

No data available

#### Other adverse effects

No data available

---

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

---

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Clotrimazole, Gentamicin)

Class : 9

Packing group : III

Labels : 9

#### IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Clotrimazole, Gentamicin)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 964

Packing instruction (passenger aircraft) : 964

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

Environmentally hazardous : yes

### IMDG-Code

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
 (Clotrimazole, Gentamicin)  
 Class : 9  
 Packing group : III  
 Labels : 9  
 EmS Code : F-A, S-F  
 Marine pollutant : yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### 49 CFR

UN/ID/NA number : UN 3082  
 Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
 (Clotrimazole, Gentamicin)  
 Class : 9  
 Packing group : III  
 Labels : CLASS 9  
 ERG Code : 171  
 Marine pollutant : yes(Clotrimazole, Gentamicin)  
 Remarks : Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

---

## SECTION 15. REGULATORY INFORMATION

### EPCRA - Emergency Planning and Community Right-to-Know

#### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Reproductive toxicity  
 Specific target organ toxicity (single or repeated exposure)

# Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 3.1      Revision Date: 04/12/2018      SDS Number: 808853-00009      Date of last issue: 10/10/2017  
Date of first issue: 07/22/2016

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

## US State Regulations

### Pennsylvania Right To Know

White mineral oil (petroleum) 8042-47-5

### California Prop. 65

WARNING: This product can expose you to chemicals including Gentamicin, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### California List of Hazardous Substances

White mineral oil (petroleum) 8042-47-5

### California Permissible Exposure Limits for Chemical Contaminants

White mineral oil (petroleum) 8042-47-5

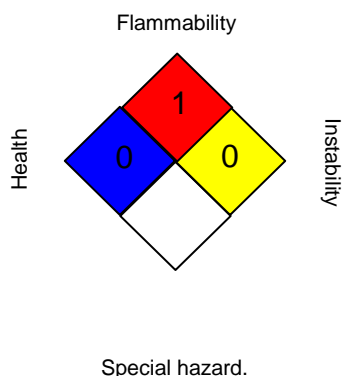
### The ingredients of this product are reported in the following inventories:

AICS : not determined  
DSL : not determined  
IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

|                 |   |   |
|-----------------|---|---|
| HEALTH          | * | 3 |
| FLAMMABILITY    |   | 1 |
| PHYSICAL HAZARD |   | 0 |

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NIOSH REL : USA. NIOSH Recommended Exposure Limits

## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

|                 |   |   |
|-----------------|---|---|
| OSHA Z-1        | : | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants          |
| ACGIH / TWA     | : | 8-hour, time-weighted average   |
| NIOSH REL / TWA | : | Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |
| NIOSH REL / ST  | : | STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday    |
| OSHA Z-1 / TWA  | : | 8-hour time weighted average  |

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 04/12/2018

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided

# SAFETY DATA SHEET



## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 10/10/2017  |
| 3.1     | 04/12/2018     | 808853-00009 | Date of first issue: 07/22/2016 |

---

relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

US / Z8