SAFETY DATA SHEETS

This SDS packet was issued with item:

078074542

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

078071203 078071211

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).

078074526

Intervet Inc.
56 Livingston Avenue
Roseland, NJ 07068

MATERIAL SAFETY DATA SHEET

Schering-Plough 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

MSDS NAME: **Mometamax Otic Suspension**

SYNONYM(S): Mometamax Otic Suspension
Mometamax Ointment

MSDS NUMBER: SP000061

EMERGENCY NUMBER(S): Schering-Plough Security Control Center (908) 820-6921 (24 hours)

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

INFORMATION: Animal Health Technical Services:
For Small Animals and Horses: (800) 224-5318
For Livestock: (800) 211-3573
For Poultry: (800) 219-9286

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

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Viscous suspension
White to off-white
Oil odor
May be an aspiration hazard if ingested (mineral oil).
Possible risk of harm to the unborn child.
Toxic to aquatic organisms.
May cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS:

The information presented below pertains to the following individual ingredients, and not to 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.

Gentamicin sulfate, an active ingredient, is an aminoglycoside antibiotic that acts by inhibiting normal protein synthesis in susceptible bacteria. Gentamicin sulfate may be irritating to the eyes and skin. It may cause damage to the nervous system and kidneys. Balance and hearing problems may occur as well as numbness and convulsions. Gentamicin sulfate may produce severe reactions in persons allergic or sensitized to aminoglycoside antibiotics. Exposure to gentamicin sulfate by individuals already using potent diuretics should be avoided.

Aminoglycosides may cross the placenta and cause fetal harm. There have been reports of total irreversible bilateral congenital deafness in children whose mothers received aminoglycosides including gentamicin during pregnancy. In animal reproduction studies, fetal kidney effects were noted at doses higher than human clincial doses. In other reproductive studies, no effects on fertility or fetal harm were observed. Small amounts of gentamicin have been shown to be excreted in breast milk.

Mometasone furoate (MF) is a very potent intranasal steroid. MF, when given as a nasal suspension or when applied as an ointment (0.1% MF) to intact skin for eight hours, without occlusion, is <1% bioavailable. Several factors including degree of occlusion, inflammation, and/or integrity of skin will increase the percutaneous absorption of topical corticosteroids. Due to its lack of bioavailability, the systemic toxicity of MF is significantly lower than that of traditional steroids and is not observed at therapeutic doses.

MF appears to have little or no effect on HPA axis function. Studies using higher than therapeutic inhaled doses up to 4 mg MF/day and oral doses up to 8 mg MF/day have not demonstrated suppression of the HPA axis. Long-term treatment with lower, recommended therapeutic doses has also been reported not to affect HPA axis function as measured by cortisol levels in plasma and urine. This observation is believed to be related to the low systemic bioavailability of MF. Reported occupational effects from mometasone furoate include allergic skin reactions such as inflammation and rash.

Mineral oil may cause irritation to the respiratory tract, skin and eyes. 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.

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

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
Clotrimazole	23593-75-1	1
Gentamicin Sulfate	1405-41-0	0.5
Mometasone Furoate	83919-23-7	0.1
Mineral Oil	8012-95-1	>90
Ethene Homopolymer (Polyethylene)	9002-88-4	<10

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.

SECTION 4. FIRST AID MEASURES

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.

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 (CO2), extinguishing powder or water spray.

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.

ENVIRONMENTAL PRECAUTIONS:
This product is toxic to aquatic organisms. Do not allow product to reach ground water, water course, sewage or drainage systems.

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.

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

S-P OCCUPATIONAL EXPOSURE GUIDELINE (OEG):
Schering-Plough Corporation has established an Occupational Exposure Guideline of 8 mcg/m^3 (8-hr TWA) for mometasone (base).

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.
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^3	5 mg/m^3

INGREDIENT	CAS NUMBER	ACGIH TLV (STEL / SKIN)	ACGIH TLV (CEIL)	OSHA PEL (STEL / SKIN)	OSHA PEL (CEIL)
Mineral Oil	8012-95-1	10 mg/m^3			

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: White to off-white
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:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition products known.

SECTION 11. TOXICOLOGICAL INFORMATION

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.

Gentamicin sulfate: LC50: > 0.20 mg/L (rat)
In an acute inhalation toxicity study, rats given 0.20 mg/L (maximum attainable concentration) exhibited labored breathing and eye closure during exposure to gentamicin sulfate. Nasal discharge was noted for several days followed by recovery.

Mometasone furoate did not cause mortality but did result in rales, ano-genital staining, emaciation and body weight losses in rats at 0.68 mg/l (maximum attainable concentration).

Ethene homopolymer: Practically not toxic.

SKIN:
Mometamax Otic Suspension was found to be non-irritating to the skin of rabbits.

EYE:
Mometamax Otic Suspension was determined to be practically non-irritating (MMTS=2.0) when administered 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)

Gentamicin sulfate: Oral LD50: > 5000 mg/kg (rat)

Mometasone: Oral LD50: >2000 mg/kg (rodent)
No clinical effects were observed following oral administration of mometasone to rats and mice.

Mineral Oil: Practically not toxic

Ethene homopolymer: Practically not toxic.

SENSITIZATION:
Clotrimatole (1%) did not produce skin sensitization in humans or animals when used in different formulations.

Mometasone was a weak sensitizer in guinea pigs.

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, conjuctivitis 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.

A subacute (2-week) study was conducted in cynomolgus monkeys with intravenous injections of gentamicin sulfate at dose levels of 2.5 to 30 mg/kg/day. Mortality was observed at 30 mg/kg following administration of the first dose. Clinical observations including hypoactivity, labored breathing, reduced body weight, and renal toxicity resulted from treatment [NOEL: 2.5 mg/kg/day]. No adverse effects were observed in rats given gentamicin sulfate for 20 mg/kg/day for 24 days or in cats given 10 mg/kg/day for 40 days. Gentamicin sulfate administered to dogs at 6 mg/lb/day, 6 days weekly for 3 weeks, caused no detectable kidney damage. At higher doses impairment of equilibrium and renal function were observed in these species.

Oral subchronic (13-14 weeks) studies with gentamicin sulfate were conducted in rats and dogs. Dose levels ranged from 3.9 to 232.8 mg/kg/day in rats and 2 to 120 mg/kg in dogs. Soft stools and abnormal urinalysis (increased ketone bodies), both in the high dose group, were the only effects noted in rats [NOEL: 19.4 mg/kg/day]. In dogs, no adverse clinical reactions were noted and liver and kidney function were normal [NOEL: 120 mg/kg].

Several repeat dose studies have been performed with mometasone furoate (MF) using rodents and dogs. The systemic effects observed after treatment with MF are fairly consistent across species and exposure routes.

One-month oral toxicity studies in rats and dogs showed changes in the thymus, mesenteric lymph nodes, liver, adrenals, and skin with a reported NOEL of 5 mcg/kg in rats and LOEL of 500 mcg/kg in dogs.

Short- and long-term inhalation studies in rats, mice and dogs were performed using doses of MF ranging from 0.02 mcg/L to 16 mcg/L. Common clinical signs observed across species included changes in body weights, adrenal glands, lungs, thymus, lymph nodes, spleen, trachea, bone marrow, kidney, and liver.

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 lipoid 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. Clortrimazole 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.

In rats and guinea pigs, fetal renal abnormalities have been reported after administration of gentamicin to the dam. In guinea pigs, transient renal abnormalities were observed in the fetus after the administration of 4 mg/kg of gentamicin to the mother. In two reproduction studies, rats were administered 75 mg/kg gentamicin (10 to 15 times the human dose) in saline for 12 days from day 10 of gestation to delivery (intraperitoneal injection) or on days 7-11 and 14-18 of pregnancy (intramuscular injection). Adverse effects reported included lesions in the developing kidney, reduced rate of early nephrogenesis, general growth retardation, and alterations of the glomeruli and proximal tubules. Other animal reproduction studies in rats did not exhibit any evidence of impaired fertility or harm to the fetus following exposure to gentamicin sulfate. No adverse effects were observed in the offspring of rabbits given 0.8 to 3.6 mg/kg intramuscularly on gestation days 6 to 16.

Aminoglycosides can cause fetal harm as they can cross the placenta, however, it is not known whether fetal harm or effects on the reproductive capacity can be caused by exposure to gentamicin sulfate by pregnant women.

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.

Developmental toxicity studies were conducted with mometasone furoate in rats, rabbits, and mice using subcutaneous, topical dermal, and oral administration. Developmental or teratogenic effects were observed in all animals (rats, mice, and rabbits) treated with dosages of mometasone furoate between 15-2800 mcg/kg.

Mometasone furoate (MF) caused cleft palate in mice given subcutaneous doses of greater than or equal to 60 mcg/kg. Offspring survival was reduced when mice were treated with 180 mcg/kg (NOEL 20 mcg/kg). No effect on fertility in rats was seen following subcutanteous administration of doses up to 15 mcg MF/kg; however, prolonged gestation, prolonged and difficult labor, reduced offspring survival and reduced maternal body weight gain were observed at 15 mcg MF/kg. Similar effects were seen in rabbits and rats following topical dermal doses of greater than or equal to 150 mcg MF/kg including: reductions in maternal body weight gain, cleft lip/palate, protruding bowel, brain and umbilical hernias and effects on fetal growth (lower fetal body weights and/or delayed ossification).

Oral doses of 700 mcg MF/kg in rabbits caused increased incidences of resorptions, cleft palate and head malformations. Following oral doses of 2800 mcg MF/kg, rabbits failed to become pregnant (resorptions).

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

Mometasone furoate was negative in the Ames bacterial mutagenicity assay, mouse-lymphoma assay, rat bone marrow clastogenicity assay, Chinese hamster lung chromosome aberration assay, and male germ cell clastogenicity assay. At cytotoxic doses, mometasone furoate produced an increase in chromosome aberrations in vitro but not in the presence of microsomal activation (rat liver S9 fraction).

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

Inhalation studies ranging from 19 months to 2 years with mometasone furoate in mice and rats did not produce statistically significant increases in tumor formation at doses of 67 and 160 mcg MF/day respectively.

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

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Clotrimazole:
96-hr LC50 (fish): >0.29 mg/L
48-hr EC50 (daphnid): 0.02 mg/L
96-hr EC50 (algae): 0.02 mg/L (biomass); 0.098 mg/L (growth rate)

ENVIRONMENTAL DATA

OTHER INGREDIENT ENVIRONMENTAL DATA:

Clotrimazole is not readily biodegradable.
log Pow (log octanol/water partition coefficient): 4.1
Water Solubility: 0.49 mg/L
Hydrolysis Rate (Half-life): 242 days at 7 deg C (pH 25)
Vapor Pressure: 3.31E-5 hPa (calculated)
Activated Sludge Respiration Inhibition: 3-hr EC50: >10,000 mg/L

SECTION 13. DISPOSAL CONSIDERATIONS

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.

SPECIAL ENVIRONMENTAL HANDLING PROCEDURES:
This product contains materials that are harmful to the environment. Do not allow product to reach ground water, water courses, sewage or drainage systems.

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
Mineral Oil	X
Ethene Homopolymer (Polyethylene)	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	CTRTK	MARTK
Mineral Oil		X			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.
D: Developmental hazard

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 and Environmental Affairs
Occupational and Environmental Toxicology
Schering Corporation
556 Morris Avenue
Summit, NJ 07901 USA

SCHERING-PLOUGH MSDS HELPLINE:

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

MSDS CREATION DATE: 18-Oct-1999

SUPERSEDES DATE: 11-Feb-2010

SECTIONS CHANGED (US SUBFORMAT): 2, 11

Merck Animal Health
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

MSDS NAME: **Mometamax Otic Suspension**

SYNONYM(S): Mometamax Otic Suspension
Mometamax Ointment

MSDS NUMBER: SP000061

EMERGENCY NUMBER(S): (908) 423-6000 (24/7/365) English Only

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

Rocky Mountain Poison Center (For Human Exposure):
(303) 595-4869

Animal Health Technical Services:
For Animal Adverse Events: Small Animals and Horses: (800) 224-5318
For Animal Adverse Events: Livestock: (800) 211-3573
For Animal Adverse Events: Poultry: (800) 219-9286

INFORMATION: Animal Health Technical Services:
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MERCK MSDS HELPLINE: (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time)

SECTION 2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

Viscous suspension
White to off-white
Oil odor
May be an aspiration hazard if ingested (mineral oil).
Possible risk of harm to the unborn child.
Toxic to aquatic organisms.
May cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS:

The information presented below pertains to the following individual ingredients, and not to 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.

Gentamicin sulfate, an active ingredient, is an aminoglycoside antibiotic that acts by inhibiting normal protein synthesis in susceptible bacteria. Gentamicin sulfate may be irritating to the eyes and skin. It may cause damage to the nervous system and kidneys. Balance and hearing problems may occur as well as numbness and convulsions. Gentamicin sulfate may produce severe reactions in persons allergic or sensitized to aminoglycoside antibiotics. Exposure to gentamicin sulfate by individuals already using potent diuretics should be avoided.

Aminoglycosides may cross the placenta and cause fetal harm. There have been reports of total irreversible bilateral congenital deafness in children whose mothers received aminoglycosides including gentamicin during pregnancy. In animal reproduction studies, fetal kidney effects were noted at doses higher than human clincial doses. In other reproductive studies, no effects on fertility or fetal harm were observed. Small amounts of gentamicin have been shown to be excreted in breast milk.

Mometasone furoate (MF) is a very potent intranasal steroid. MF, when given as a nasal suspension or when applied as an ointment (0.1% MF) to intact skin for eight hours, without occlusion, is <1% bioavailable. Several factors including degree of occlusion, inflammation, and/or integrity of skin will increase the percutaneous absorption of topical corticosteroids. Due to its lack of bioavailability, the systemic toxicity of MF is significantly lower than that of traditional steroids and is not observed at therapeutic doses.

MF appears to have little or no effect on HPA axis function. Studies using higher than therapeutic inhaled doses up to 4 mg MF/day and oral doses up to 8 mg MF/day have not demonstrated suppression of the HPA axis. Long-term treatment with lower, recommended therapeutic doses has also been reported not to affect HPA axis function as measured by cortisol levels in plasma and urine. This observation is believed to be related to the low systemic bioavailability of MF. Reported occupational effects from mometasone furoate include allergic skin reactions such as inflammation and rash.

Mineral oil may cause irritation to the respiratory tract, skin and eyes. 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.

LISTED CARCINOGENS

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

No carcinogens or potential carcinogens listed by OSHA, IARC, NTP or ACGIH are present in concentrations >0.1% in this mixture.

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

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
Clotrimazole	23593-75-1	1
Gentamicin Sulfate	1405-41-0	0.5
Mometasone Furoate	83919-23-7	0.1
Mineral Oil	8012-95-1	>90
Ethene Homopolymer (Polyethylene)	9002-88-4	<10

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.

SECTION 4. FIRST AID MEASURES

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.

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 (CO2), extinguishing powder or water spray.

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.

ENVIRONMENTAL PRECAUTIONS:
This product is toxic to aquatic organisms. Do not allow product to reach ground water, water course, sewage or drainage systems.

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

OCCUPATIONAL EXPOSURE GUIDELINE (OEG):
An Occupational Exposure Guideline of 8 mcg/m^3 (8-hr TWA) has been established for mometasone (base).

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.
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^3	5 mg/m^3

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: White to off-white
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:
None known.

HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:
No dangerous decomposition products known.

SECTION 11. TOXICOLOGICAL INFORMATION

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.

Gentamicin sulfate: LC50: > 0.20 mg/L (rat)
In an acute inhalation toxicity study, rats given 0.20 mg/L (maximum attainable concentration) exhibited labored breathing and eye closure during exposure to gentamicin sulfate. Nasal discharge was noted for several days followed by recovery.

Mometasone furoate did not cause mortality but did result in rales, ano-genital staining, emaciation and body weight losses in rats at 0.68 mg/l (maximum attainable concentration).

Ethene homopolymer: Practically not toxic.

SKIN:
Mometamax Otic Suspension was found to be non-irritating to the skin of rabbits.

EYE:
Mometamax Otic Suspension was determined to be practically non-irritating (MMTS=2.0) when administered 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)

Gentamicin sulfate: Oral LD50: > 5000 mg/kg (rat)

Mometasone: Oral LD50: >2000 mg/kg (rodent)
No clinical effects were observed following oral administration of mometasone to rats and mice.

Mineral Oil: Practically not toxic

Ethene homopolymer: Practically not toxic.

DERMAL AND RESPIRATORY SENSITIZATION:
Clotrimatole (1%) did not produce skin sensitization in humans or animals when used in different formulations.

Mometasone was a weak sensitizer in guinea pigs.

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, conjuctivitis 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.

A subacute (2-week) study was conducted in cynomolgus monkeys with intravenous injections of gentamicin sulfate at dose levels of 2.5 to 30 mg/kg/day. Mortality was observed at 30 mg/kg following administration of the first dose. Clinical observations including hypoactivity, labored breathing, reduced body weight, and renal toxicity resulted from treatment [NOEL: 2.5 mg/kg/day]. No adverse effects were observed in rats given gentamicin sulfate for 20 mg/kg/day for 24 days or in cats given 10 mg/kg/day for 40 days. Gentamicin sulfate administered to dogs at 6 mg/lb/day, 6 days weekly for 3 weeks, caused no detectable kidney damage. At higher doses impairment of equilibrium and renal function were observed in these species.

Oral subchronic (13-14 weeks) studies with gentamicin sulfate were conducted in rats and dogs. Dose levels ranged from 3.9 to 232.8 mg/kg/day in rats and 2 to 120 mg/kg in dogs. Soft stools and abnormal urinalysis (increased ketone bodies), both in the high dose group, were the only effects noted in rats [NOEL: 19.4 mg/kg/day]. In dogs, no adverse clinical reactions were noted and liver and kidney function were normal [NOEL: 120 mg/kg].

Several repeat dose studies have been performed with mometasone furoate (MF) using rodents and dogs. The systemic effects observed after treatment with MF are fairly consistent across species and exposure routes.

One-month oral toxicity studies in rats and dogs showed changes in the thymus, mesenteric lymph nodes, liver, adrenals, and skin with a reported NOEL of 5 mcg/kg in rats and LOEL of 500 mcg/kg in dogs.

Short- and long-term inhalation studies in rats, mice and dogs were performed using doses of MF ranging from 0.02 mcg/L to 16 mcg/L. Common clinical signs observed across species included changes in body weights, adrenal glands, lungs, thymus, lymph nodes, spleen, trachea, bone marrow, kidney, and liver.

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 lipoid 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. Clortrimazole 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.

In rats and guinea pigs, fetal renal abnormalities have been reported after administration of gentamicin to the dam. In guinea pigs, transient renal abnormalities were observed in the fetus after the administration of 4 mg/kg of gentamicin to the mother. In two reproduction studies, rats were administered 75 mg/kg gentamicin (10 to 15 times the human dose) in saline for 12 days from day 10 of gestation to delivery (intraperitoneal injection) or on days 7-11 and 14-18 of pregnancy (intramuscular injection). Adverse effects reported included lesions in the developing kidney, reduced rate of early nephrogenesis, general growth retardation, and alterations of the glomeruli and proximal tubules. Other animal reproduction studies in rats did not exhibit any evidence of impaired fertility or harm to the fetus following exposure to gentamicin sulfate. No adverse effects were observed in the offspring of rabbits given 0.8 to 3.6 mg/kg intramuscularly on gestation days 6 to 16.

Aminoglycosides can cause fetal harm as they can cross the placenta, however, it is not known whether fetal harm or effects on the reproductive capacity can be caused by exposure to gentamicin sulfate by pregnant women.

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.

Developmental toxicity studies were conducted with mometasone furoate in rats, rabbits, and mice using subcutaneous, topical dermal, and oral administration. Developmental or teratogenic effects were observed in all animals (rats, mice, and rabbits) treated with dosages of mometasone furoate between 15-2800 mcg/kg.

Mometasone furoate (MF) caused cleft palate in mice given subcutaneous doses of greater than or equal to 60 mcg/kg. Offspring survival was reduced when mice were treated with 180 mcg/kg (NOEL 20 mcg/kg). No effect on fertility in rats was seen following subcutanteous administration of doses up to 15 mcg MF/kg; however, prolonged gestation, prolonged and difficult labor, reduced offspring survival and reduced maternal body weight gain were observed at 15 mcg MF/kg. Similar effects were seen in rabbits and rats following topical dermal doses of greater than or equal to 150 mcg MF/kg including: reductions in maternal body weight gain, cleft lip/palate, protruding bowel, brain and umbilical hernias and effects on fetal growth (lower fetal body weights and/or delayed ossification).

Oral doses of 700 mcg MF/kg in rabbits caused increased incidences of resorptions, cleft palate and head malformations. Following oral doses of 2800 mcg MF/kg, rabbits failed to become pregnant (resorptions).

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

Mometasone furoate was negative in the Ames bacterial mutagenicity assay, mouse-lymphoma assay, rat bone marrow clastogenicity assay, Chinese hamster lung chromosome aberration assay, and male germ cell clastogenicity assay. At cytotoxic doses, mometasone furoate produced an increase in chromosome aberrations in vitro but not in the presence of microsomal activation (rat liver S9 fraction).

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

Inhalation studies ranging from 19 months to 2 years with mometasone furoate in mice and rats did not produce statistically significant increases in tumor formation at doses of 67 and 160 mcg MF/day respectively.

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

SECTION 12. ECOLOGICAL INFORMATION

There are no data for the final product or its formulation(s). The information presented below pertains to the following ingredient(s).

ECOTOXICITY DATA

INGREDIENT ECOTOXICITY

Clotrimazole:
96-hr LC50 (fish): >0.29 mg/L
48-hr EC50 (daphnid): 0.02 mg/L
96-hr EC50 (algae): 0.02 mg/L (biomass); 0.098 mg/L (growth rate)

ENVIRONMENTAL DATA

OTHER INGREDIENT ENVIRONMENTAL DATA:

Clotrimazole is not readily biodegradable.
log Pow (log octanol/water partition coefficient): 4.1
Water Solubility: 0.49 mg/L
Hydrolysis Rate (Half-life): 242 days at 7 deg C (pH 25)
Vapor Pressure: 3.31E-5 hPa (calculated)
Activated Sludge Respiration Inhibition: 3-hr EC50: >10,000 mg/L

SECTION 13. DISPOSAL CONSIDERATIONS

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.

SPECIAL ENVIRONMENTAL HANDLING PROCEDURES:
This product contains materials that are harmful to the environment. Do not allow product to reach ground water, water courses, sewage or drainage systems.

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
Mineral Oil	X
Ethene Homopolymer (Polyethylene)	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	CTRTK	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.
D: Developmental hazard

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).

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