SAFETY DATA SHEET

OTOMAX®

Section 1: Identification of the Substance and Supplier

Product name	**Otomax** Cream containing 0.1 – 0.3% betamethasone valerate, 0.7 – 1.3% clotrimazole and 0.2 – 0.5% gentamicin sulphate.
Recommended use	Veterinary treatment for dogs.
Company details	**MSD Animal Health, 33 Whakatiki Street, Upper Hutt** **Phone: 0800 800 543 Fax: 0800 808 100** **Website: www.msd-animal-health.co.nz** **Hours: 8 am – 5 pm, Mon – Fri**
Emergency telephone	**0800 764 766 (0800 POISON) 24 hours human health** **0800 243 622 (0800 CHEMCALL) 24 hours**
Date of preparation	September 2011

Section 2: Hazards Identification

Hazard classifications	6.5B, 6.8B
Priority identifiers	**WARNING**
Secondary identifier	6.5B May cause an allergic skin reaction 6.8B Suspected of damaging fertility or the unborn child from repeated oral exposure
Risk & Safety Phrases	R63 Possible risk of harm to the unborn child

Section 3: Composition/Information on Ingredients

Chemical name	CAS number	Concentration
Gentamicin sulphate	1405-41-0	<0.5%
Betamethasone valerate	2152-44-5	0.12%
Clotrimazole	23593-75-1	1.0%
Mineral oil	8012-95-1	65 – 75%

Section 4: First Aid Measures

Necessary first aid measures

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 doctor.

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 doctor.

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 Centre. If symptoms persist, consult a doctor.

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 doctor.
Required instructions	For advice contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor.
Notes for medical personnel	This product contains clotrimazole, a broad spectrum antifungal agent, and betamethasone diproprionate, a steroid hormone. This product is indicated for the tropical treatment of dermal infections. Person 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

Type of hazard	Not classified as flammable
Fire hazard properties	Not applicable
Regulatory requirements	Not applicable
Extinguishing media and methods	Carbon dioxide (CO_2), extinguishing powder or water spray.
Hazchem code	Not applicable
Recommended protective clothing	Wear full protective clothing and self-contained breathing apparatus (SCBA).

Section 6: Accidental Release Measures

Emergency procedures	Wear chemical resistant gloves and overalls, facemask or goggles. Prevent further spillage. Adsorb spilled product and place in sealable container for disposal. Wash down affected area with water plus detergent. Absorb and collect washings and place in the same sealable container for disposal. Seek advice from the local authority regarding disposal.

Section 7: Handling and Storage

Precautions for safe handling	Avoid contact with skin, eyes, and mucosa. Keep containers adequately sealed during material transfer, transport, or when not in use. See Section 8 (Exposure Controls) for additional guidance.
Regulatory requirements	Emergency Plan required where quantities greater than 1000L are present.
Handling practices	Avoid contact with skin. Keep containers adequately sealed during material transfer, transport, or when not in use.
Approved handlers	Not required
Conditions for safe storage	Store in original container in a cool, dry, ventilated place away from direct heat or direct sunlight. Keep container sealed when not in use. Keep out of reach of children.
Store site requirements	Store below 25°C.
Packaging	Schedule 4

Section 8: Exposure Control/Personal Protection

Workplace exposure standards	Mineral Oil: TWA 5 mg/m^3 Mist
Application in the workplace	Ensure adequate ventilation. Keep container sealed when not in use.
Exposure standards outside the workplace	No TEL is set for this substance at this time EEL – not applicable
Personal protection	Wear chemical resistant gloves, facemask or goggles.

Section 9: Physical and Chemical Properties

Appearance	Smooth, uniform, white to off-white viscous suspension
Boiling Point	Not applicable
Melting/Softening point	Not determined
Vapour Pressure	Not applicable
Specific Gravity	Not applicable
Solubility (H_2O)	Not determined
Percent Volatiles	Not applicable
Evaporation Rate	Not applicable

Section 10: Stability and Reactivity

Stability of the substance	Stable under normal conditions.
Conditions to avoid	Open flames and extremes of temperature.
Material to avoid	Avoid food products. Oxidisers. Strong acids and bases.
Hazardous decomposition products	Carbon oxides (COx).

Section 11: Toxicological Information

Acute effects for individual ingredients only

ORAL	Clotrimazole: LD50 708 mg/kg (rat); 761-923 mg/kg (mouse); >1000 mg/kg (rabbit & dog). Betamethasone dipropionate: LD50 >5000 mg/kg (rat); >50 mg/kg (mouse); >1000 mg/kg (dog).
DERMAL	Mineral oil is slightly irritating to the skin of rabbits.
TEL	No TEL is set for this substance at this time.

Chronic/long term effects for individual ingredients only

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). 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 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 haematological, biochemical and physiological data (increased fluid intake and urinary output, decreased hematocrit and haemoglobin 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 lipoid granules.

REPRODUCTIVE / DEVELOPMENTAL TOXICITY:
High oral doses of clotrimazole in rats and mice (ranging from 50 – 1250 mg/Kg) resulted in embryotoxicity (possibly secondary to maternal toxicity), impairment of mating, decreased litter size and number of viable young and decrease pup survival to weaning.
Coricosteroids 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, occurence 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 diproprionate 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 adrenocorticotropic 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.

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

Section 12: Environmental Information

Effects for individual ingredients only

EEL	Not applicable

Section 13: Disposal Considerations

Disposal information

Disposal
Dispose of unused contents in a suitable landfill.

Container Disposal
Dispose of empty container by burying in a suitable landfill.

Reference

Current version of NZS 8409 Management of Agrichemicals

Section 14: Transport Information

Relevant information

Not classified as a dangerous good for transport

Section 15: Regulatory Information

Regulatory status

ACVM Registration No: A7883
For conditions of registration see www.foodsafety.govt.nz

HSNO Approval Code: HSR002094.

RESTRICTED VETERINARY MEDICINE

HSNO and ACVM controls

Emergency Plan: 1000 Litres

Section 16: Other Information

Additional information

Otomax is a registered trademark.