

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name: STOMORGYL 2, 10, 20
Product code: A6397, A5098, and A6817 respectively.
Recommended use: For the treatment of infections caused by susceptible aerobic and anaerobic bacteria in dogs.
Company details: Merial Ancare
Address: Level 3, Merial Building
Osterley Way
Manukau City
New Zealand
Telephone number: Phone: +64 9 980 1600 Fax: +64 9 980 1601
Emergency telephone number: Merial Ancare Freephone: 0800 800 822
National Poisons Centre: 0800 764 766 (0800 POISON)
Fire Service, Ambulance: Dial 111
Date of preparation: 13 September 2007

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Antibiotic

Product components:

<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Metronidazole	443-48-1	-20%
Spiramycin	8025-81-8	-29%

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications: 6.1E, 6.5B, 6.6A, 6.7B, 9.1A
Priority and secondary identifiers: Harmful – keep out of reach of children
Ecotoxic
Risk and safety phrases: May be harmful if swallowed, inhaled or absorbed through the skin. Wash hands and exposed skin before meals and after use
Warning – Repeated exposure may cause skin allergy. Wash hands after use
Toxic – may cause heritable mutations/genetic defects
Harmful – suspected of causing cancer
Ecotoxic – Very toxic to aquatic organisms. Avoid contamination of any water supply with product or empty container.

SECTION 4: FIRST AID MEASURES

Necessary first aid measures: **For advice contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor immediately.**
Eye Contact: Hold eyelids apart and flush the eye continuously with running water for at least 15 minutes. Get medical attention.
Inhalation: Remove patient to fresh air. If not breathing, give artificial respiration, preferably mouth-to-nose. Get medical attention if symptoms develop.
Ingestion: Do NOT induce vomiting. See medical advice immediately.
Workplace facilities: N/A

Required instructions:	N/A
Notes for medical personnel:	In case of symptomatic effect provide treatment to maintain life functions.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:	Product is not self-igniting and does not present an explosion hazard.
Fire hazard properties:	During a fire toxic fumes may be released.
Regulatory requirements:	N/A
Extinguishing media and methods:	Extinguish fires with foam, dry chemical or carbon dioxide. Cool sealed drums with water to prevent rupture due to thermal expansion. Contain run-off. Keep non-involved persons away.
Hazchem code:	N/A
Recommended protective clothing:	Wear PVC protective clothing and breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:	Wear overalls, chemical resistant gloves, boots and safety goggles. Prevent further spillage. Sweep up solids without generating dust. Wash down affected area with water plus detergent. Absorb and collect washings and place in the same sealable container for disposal. Do not allow product to reach natural waterways or sewers. Seek advice from the local authority regarding disposal.
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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	N/A
Regulatory requirements:	N/A
Handling practices:	N/A
Approved handlers:	Not required
Conditions for safe storage:	Store in original container in a locked, dry, cool area away from foodstuffs, children and animals. Keep container sealed when not in use.
Store site requirements:	N/A
Packaging:	N/A

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
Application in the workplace:	N/A
Exposure standards outside the workplace:	N/A
Engineering controls:	N/A
Personal protection:	Keep away from foodstuffs, beverages. Wash hands before breaks and at the end of work. Avoid contact with the eyes. Do not eat, drink, smoke or inhale. Do not store food in the working area
References:	N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:	<u>Appearance:</u> Solid pink tablets <u>Solubility:</u> Insoluble in water
Required specifications:	N/A
Further specifications:	N/A
Specific advice:	N/A

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable under normal conditions
Conditions to avoid:	N/A
Material to avoid:	N/A
Hazardous decomposition products:	N/A
Hazardous polymerization:	Will not occur
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation:	<u>Spiramycin</u> Oral LD50 2900 mg/kg (mouse) 3550 mg/kg (rat)
Summaries data:	N/A
Effects of Acute Exposure:	Acute and sub acute toxicity trials have shown that spiramycin and metronidazole, separately and in combination, have low toxicity. <u>Ingestion:</u> Acute toxic effects would not be expected. Human patients have been administered doses of 2g daily without ill effect <u>Skin Contact:</u> There is no evidence from studies that metronidazole is either a skin irritant or a skin sensitising agent.
Effects of Chronic Exposure:	Chronic toxicity trials in two laboratory species have shown that a 2:1 mixture of spiramycin and metronidazole administered for one month at twice the recommended dose rate was well tolerated. No significant effects were seen in dogs treated daily for 4 weeks at doses up to 150 mg/kg/day. The study concluded that an overt toxicity with a specific target organ or target function cannot be attributed to the treatment. No teratogenicity in the laboratory animal species tested

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:	Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
Data organisation :	N/A
Environmental risk and safety phrases:	Environmentally hazardous substance, Solid, N.O.S. (ivermectin)

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :	Seek disposal instructions from local authority or arrange with a licensed waste contractor.
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SECTION 14: TRANSPORT INFORMATION

Relevant information:	DG Class 9 for road transport UN 3077
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Other requirements:	Tracking not required. N/A
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SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No.s, A6397, A5098, and A6817. See www.nzfsa.govt.nz/acvm for registration conditions. Approved pursuant to the HSNO Act 1996, Approval Code HSR002121 and HSR002122. See www.ermanz.govt.nz for approval conditions.
HSNO and ACVM controls:	Refer to Section 3
List exposure limits:	N/A

SECTION 16: OTHER INFORMATION

Additional information:	For product information visit the Merial website www.merial.co.nz While the information set forth is believed to be accurate as of the date hereof, MERIAL NZ LTD. makes no warranty with respect hereto and disclaims all liability from reliance thereon.
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