

**SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER**

<b>Product name:</b>	<b>STOMORGYL 20</b>
<b>Product code:</b>	A006817
<b>Recommended use:</b>	For the treatment of infections caused by susceptible aerobic and anaerobic bacteria in dogs.
<b>Company details:</b>	Boehringer Ingelheim Animal Health New Zealand Limited
<b>Address:</b>	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City Auckland 2104 New Zealand
<b>Telephone number:</b>	Phone: +64 9 263 1400
<b>Emergency telephone number:</b>	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre: 0800 764 766 (0800 POISON) Fire Service, Ambulance: Dial 111
<b>Date of issue:</b>	13 September 2007
<b>Date of review:</b>	7 February 2020

**SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS**

<b>Chemical characterization:</b>	Antibiotic	
<b>Product components:</b>		
<b><u>Name</u></b>	<b><u>CAS</u></b>	<b><u>Proportion</u></b>
Metronidazole	443-48-1	10-30%
Spiramycin	8025-81-8	30-60%

**SECTION 3: HAZARDS IDENTIFICATION**

<b>Hazard classifications:</b>	6.1E, 6.5B, 6.6A, 6.7B, 9.1A
<b>Priority and secondary identifiers:</b>	Harmful – keep out of reach of children <b>Ecotoxic</b>
<b>Risk and safety phrases:</b>	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**

<b>Necessary first aid measures:</b>	<b>For advice, contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor immediately.</b>  <u>Eye Contact:</u> Hold eyelids apart and flush the eye continuously with running water for at least 15 minutes. Get medical attention.  <u>Inhalation:</u> Remove patient to fresh air. If not breathing, give artificial respiration, preferably mouth-to-nose. Get medical attention if symptoms develop.  <u>Ingestion:</u> Do NOT induce vomiting. See medical advice
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<b>Workplace facilities:</b>	immediately.
<b>Required instructions:</b>	N/A
<b>Notes for medical personnel:</b>	In case of symptomatic effect provide treatment to maintain life functions.

### SECTION 5: FIRE FIGHTING MEASURES

<b>Type of hazard:</b>	Product is not self-igniting and does not present an explosion hazard.
<b>Fire hazard properties:</b>	During a fire toxic fumes may be released.
<b>Regulatory requirements:</b>	N/A
<b>Extinguishing media and methods:</b>	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.
<b>Hazchem code:</b>	N/A
<b>Recommended protective clothing:</b>	Wear PVC protective clothing and breathing apparatus.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

<b>Emergency procedures:</b>	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

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

### SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

<b>Workplace exposure standards:</b>	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
<b>Application in the workplace:</b>	N/A
<b>Exposure standards outside the workplace:</b>	N/A
<b>Engineering controls:</b>	N/A
<b>Personal protection:</b>	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

<b>References:</b>	N/A
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### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

### SECTION 10: STABILITY AND REACTIVITY

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

### SECTION 11: TOXICOLOGICAL INFORMATION

<b>Data and interpretation:</b>	<u>Spiramycin</u> Oral LD50 2900 mg/kg (mouse) 3550 mg/kg (rat)
<b>Summaries data:</b>	N/A
<b>Effects of Acute Exposure:</b>	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.
<b>Effects of Chronic Exposure:</b>	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

<b>Potential environmental interactions:</b>	Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
<b>Data organisation :</b>	N/A
<b>Environmental risk and safety phrases:</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

### SECTION 13: DISPOSAL CONSIDERATIONS

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

<b>Relevant information:</b>	Dangerous Goods for transport. ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. UN Number: 3077 Dangerous Goods Class: 9
<b>Other requirements:</b>	Tracking not required. N/A

**SECTION 15: REGULATORY INFORMATION**

<b>Regulatory status:</b>	Registered pursuant to the ACVM Act 1997, No. A006817. See <a href="http://www.foodsafety.govt.nz">www.foodsafety.govt.nz</a> for registration conditions.
<b>HSNO and ACVM controls:</b>	Approved pursuant to the HSNO Act 1996, Approval Code HSR002122. See <a href="http://www.epa.govt.nz">www.epa.govt.nz</a> for approval conditions.
<b>List exposure limits:</b>	Refer to Section 3 N/A

**SECTION 16: OTHER INFORMATION**

<b>Additional information:</b>	For product information visit the Boehringer Ingelheim website <a href="http://www.boehringer-ingelheim.co.nz">www.boehringer-ingelheim.co.nz</a>  While the information set forth is believed to be accurate as of the date hereof, BOEHRINGER INGELHEIM makes no warranty with respect hereto and disclaims all liability from reliance thereon.
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