

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	KETOFEN tablets 5mg, 20mg
Product code:	A6613, A6615
Recommended use:	For the treatment of painful inflammatory conditions and for symptomatic treatment of febrile conditions in dogs and cats.
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:	Non steroidal anti inflammatory.	
Product components:		
<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Ketoprofen	22071 - 15 - 4	5mg or 20mg/tablet
Microcrystalline cellulose	9004 - 34 - 6	
Maltodextrin saccharose		
Magnesium stearate	557 - 04 - 0	
Lactose	63 - 42 - 3	qs

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.1D, 6.3B, 9.3C
Priority and secondary identifiers:	Harmful – keep out of reach of children
Risk and safety phrases:	Harmful – may be harmful if swallowed, inhaled or absorbed through the skin. Do not eat, drink or smoke while using. Warning – may cause mild skin irritation. Wash hands after contact. Toxic to terrestrial vertebrates.

SECTION 4: FIRST AID MEASURES

Necessary first aid measures: **For advice, contact the National Poisons Centre 0800 POISON (0800 764766) 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: If accidentally ingested seek medical attention. Decision on treatment will depend on the quantity of tablets ingested. Do NOT induce vomiting.

Workplace facilities: N/A

Required instructions: N/A

Notes for medical personnel: N/A

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: CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

Hazchem code: N/A

Recommended protective clothing: Wear PVC protective clothing and breathing apparatus. Cool sealed drums with water to prevent rupture due to thermal expansion. Contain run-off. Keep non-involved persons away.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures: Use suitable protective equipment. Contact emergency response personnel for large spills. Keep unnecessary persons away.

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 cool, dry place in tightly closed containers.

Store site requirements: N/A

Packaging: N/A

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure N/A

standards:

Application in the workplace:	N/A
Exposure standards outside the workplace:	N/A
Engineering controls:	N/A
Personal protection:	Protective equipment not required under normal conditions of use.
References:	N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:	<u>Appearance:</u> White cylindrical tablet with a sectile groove. Each tablet contains 5 mg or 20 mg Ketoprofen.
Specific advice:	N/A

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable under normal conditions of use.
Conditions to avoid:	N/A
Material to avoid:	N/A
Hazardous decomposition products:	During a fire toxic fumes may be released.
Hazardous polymerization:	Will not occur
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation:	N/A
Summaries data:	N/A
Effects of Acute Exposure:	<p>The acute toxicity of ketoprofen has been studied in the rabbit, rat, mouse and dog by oral and parenteral routes.</p> <p style="padding-left: 40px;">Intramuscular LD 50 (dog) is approximately 600 mg/kg.</p> <p style="padding-left: 40px;">Oral LD 50 (dog) is above 1000 mg/kg.</p> <p style="padding-left: 40px;">At extreme doses the following symptoms have been recorded:</p> <p style="padding-left: 80px;">vomiting, diarrhoea, ataxia, polyuria, pallor and death.</p>
Effect of Chronic Exposure:	<p>Daily administrations of 2 and 6 mg/kg/day for 5 weeks orally without producing any major clinical, paraclinical or histological effects. The higher doses of 18 and 36 mg/kg/d were toxic, mainly to the stomach (ulceration), with lesser effects on the intestines.</p> <p style="padding-left: 40px;">Ketoprofen administered at a dosage rate of 24 mg/kg/day, orally, for 6 weeks has no clinical, haematological and biochemical effect in the baboon. Intramuscular ketoprofen does not exhibit systemic toxicity in the baboon at doses up to 18 mg/kg/day for 26 weeks.</p>

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:	N/A
Data organisation :	N/A
Environmental risk and safety phrases:	Not deemed hazardous to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :	Use suitable protective equipment. Contact emergency response personnel for large spills. Keep unnecessary persons away.
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SECTION 14: TRANSPORT INFORMATION

Relevant information:	Material is NOT classed as hazardous for transport by any route.
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No.s, A6613, A6615 See www.nzfsa.govt.nz/acvm for registration conditions. Approved pursuant to the HSNO Act 1996, Approval Code HSR002050. 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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