

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	EXTENDER Max
Product code:	A9463
Recommended use:	A controlled release anthelmintic capsule for protection against major internal parasites of sheep.
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:	Polypropylene capsule containing albendazole and ivermectin tablets		
Product components:			
	<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
	Albendazole	54965-21-8	2.8g/capsule
	Ivermectin	70288-86-7	81mg/capsule
	Ingredients deemed to be non-hazardous		qs

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.1C, 6.1D, 6.5B, 6.6B, 6.8A , 6.8C, 6.9B, 9.1A, 9.2B, 9.3B, 9.3C, 9.4A
Priority and secondary identifiers:	Harmful – keep out of reach of children Ecotoxic
Risk and safety phrases:	May be dangerous if swallowed, inhaled or absorbed through the skin. Do not eat, drink or smoke while using. Wear protective clothing such as impervious gloves, waterproof hat, coat and trousers when using. Remove protective clothing and wash hands and face thoroughly before meals and after work.

Harmful – may be harmful if swallowed, inhaled or absorbed through the skin.

Do not eat, drink or smoke while using. Wear protective clothing such as impervious gloves, waterproof hat, coat and trousers when using.

Remove protective clothing and wash hands and face thoroughly before meals and after work.

Warning – Repeated exposure may cause skin allergy. Avoid skin contact.

Harmful – suspected of causing heritable mutations/genetic defects

Toxic – may cause reproductive/development damage from repeated oral exposure

Harmful – May cause organ damage from repeated oral exposure at high doses

Ecotoxic – Very toxic to aquatic organisms. Avoid contamination of any water supply with product or empty container.

Toxic to the soil environment.

Toxic to terrestrial vertebrates.

Harmful to terrestrial vertebrates. Apply only as directed. Avoid contact with skin

Very toxic to terrestrial invertebrates. Apply only as directed

SECTION 4: FIRST AID MEASURES

Necessary first aid measures:	<p>Contact the National Poisons Information Centre for further information: 0800 POISON (0800 764 766)</p> <p><u>Eye Contact:</u> Flush eyes with plenty of water for 15 minutes holding eyelids open if necessary. Seek medical assistance if irritation persists.</p> <p><u>Skin Contact:</u> Immediately flush body and clothes with large amounts of water. Remove contaminated clothing and footwear. Wash affected areas with soap and water. If a large area is affected seek medical assistance.</p> <p><u>Inhalation:</u> Remove patient to fresh air. Lie down and keep warm and rested. If breathing is shallow or has stopped ensure airway is clear and apply resuscitation. Seek medical assistance immediately.</p> <p><u>Ingestion:</u> Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Seek medical assistance immediately.</p> <p><u>Other First Aid:</u> For all routes of exposure, dilution is essential.</p>
Workplace facilities:	N/A
Required instructions:	N/A
Notes for medical personnel:	<p>Treat symptomatically. In case of symptomatic effect provide treatment to maintain life functions.</p> <p>Note that the capsule has been designed to remain in the</p>

gut of animals and that the contents of the capsule have been specifically designed for slow release over a period of 100 days. The only immediate danger would appear to be from obstructions caused by the complete capsule or individual capsule components.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:	Will burn if involved in a fire but not considered to be a significant fire risk
Fire hazard properties:	Hazardous thermal decomposition products may include sulphur oxides and nitrogen oxides. When heated to decomposition toxic fumes of carbon monoxide, carbon dioxide, formaldehyde and acrolein may be generated.
Regulatory requirements:	N/A
Extinguishing media and methods:	Extinguish fires with water fog, alcohol 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:	2X
Recommended protective clothing:	Firefighters should wear self-contained breathing apparatus and full protective equipment.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:	Vacuum, shovel or sweep up spilled material and place in an appropriate sealable container for disposal in an approved landfill. Contact emergency response personnel for large spills. Keep unnecessary persons away. Ivermectin is very toxic to certain aquatic species. Do not allow product or washings to enter natural waterways, sewers or areas draining into potable water supplies. If spill does enter waterways contact the local authority. Residual surface material should be removed with towels moistened with methanol. Incinerate all spilled materials and residues at temperatures greater than 500°C.
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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	Wash hands thoroughly after use.
Regulatory requirements:	N/A
Handling practices:	N/A
Approved handlers:	Not required
Conditions for	Store away from foodstuffs, children and animals. Store in original packaging in a dry place away from direct heat.

safe storage:	Protect from light. Store below 30°C. Keep container sealed when not in use.
Store site requirements:	N/A
Packaging:	N/A

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:	Albendazole Permissible in-house exposure limit (PIEL) = 0.3mg/mL
Application in the workplace:	N/A
Exposure standards outside the workplace:	N/A
Engineering controls:	N/A
Personal protection:	Avoid contact with contents of capsule. Wash hands thoroughly after handling and before eating, drinking or smoking. Use rubber gloves in cases of excessive overexposure.
References:	N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:	<u>Appearance:</u> Polypropylene capsule containing 10 yellowish white compressed tablets. <u>Odour:</u> Nil odour
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:	Oxidising materials.
Hazardous decomposition products:	If involved in a fire, toxic gases including carbon monoxide and carbon dioxide may be generated.

Hazardous polymerization:	N/A
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation:	<p>Low exposure risk in capsule form.</p> <p>Adverse effects may include abdominal pain, diarrhoea, nausea, vomiting and hair loss.</p> <p>NOTE: Pregnant females should not be exposed to dust and mist. Animal studies show teratogenic effects in rats and rabbits at doses of 10mg/kg/day albendazole during the first half of pregnancy.</p>
Summaries data:	<p>In a chronic study in rats given doses of 20mg/kg/day, albendazole produced slightly reduced leukocyte and neutrophil counts. In mice, degeneration of tubular epithelium of testes was observed following chronic dosing of 400mg/kg/day albendazole. Administration of doses of 10mg/kg/day albendazole for one month in humans receiving treatment for parasitic infestation has resulted in reversible abnormalities in liver function tests</p>
Effect of Acute Exposure	<p><u>Eye Contact:</u> Under normal conditions of use, no eye contact is expected with this formulation. Low exposure risk in capsule form. Powder or granules may cause physical irritation.</p> <p><u>Skin Contact:</u> Low exposure risk in capsule form. Ivermectin is non-irritating in animal studies. Although skin absorption of this formulation of ivermectin is not established, it has been shown that less than 1% of the closely related compound abamectin is absorbed through the skin of rhesus monkeys when it is applied as emulsifiable concentrate or suspended in alcohol.</p> <p><u>Inhalation:</u> Under normal conditions of use, no eye contact is expected with this formulation. No toxicity has been observed by this route of exposure to ivermectin.</p> <p><u>Ingestion:</u> The capsule contents are moderately toxic by ingestion.</p> <p>Absorption of Albendazole is likely in the case of individual tablets being swallowed. May have no effect in acute exposure. However, may cause dizziness, headache, abdominal and epigastric pain, constipation, diarrhoea, nausea and vomiting. Pruritis and rash may occur. In animals, toxic doses are associated with anorexia and lethargy, pulmonary haemorrhage and oedema, hepatic and epicardial haemorrhage.</p> <p>Pure ivermectin is considered highly toxic in acute animal studies. The acute oral toxicity studies of ivermectin have shown clear differences among species in sensitivity to ivermectin toxicity. Rodents are uniquely sensitive compared to the other species in which the compound has been tested. It is therefore inappropriate to base human risk assessment on the response in mice. Ivermectin is used at a therapeutic dose of 200mcg/kg in a variety of species, including human. Ivermectin can be excreted in milk.</p> <p>If overdosed to ivermectin, symptoms may include</p>

Effect of Chronic Exposure:	<p>decreased activity, slow rate of breathing, dilation of the pupils, muscle tremors, and incoordination.</p> <p>Unknown for product mixture. When this product is used according to the directions, prolonged exposure of man is not expected. Ivermectin has tested negative in several mutagenicity studies. Ivermectin was administered to dogs daily for 3 months and to monkeys daily for 2 weeks. In dogs there was no effect up to 500mcg/kg/day and in adult rhesus monkeys there was no effect at the maximum dosage used 1.2mg/kg/day. At higher doses in dogs there was dilation of the pupils, and at still higher doses tremor and anorexia were noted. Ivermectin can be given during gestation in horses, cattle, pigs and sheep.</p>
Carcinogen Designation:	<p>An antioxidant used in this formulation (0.01%) is listed by the International Agency for Research on Cancer as a possible carcinogen (Group 2B): no human data, animal evidence – sufficient. The antioxidant is also listed by the National Toxicology Program as a material anticipated to be a carcinogen.</p>

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:	N/A
Data organisation :	<p>Ivermectin: LC50 (Daphnia Magna) = 36 ppt (parts per trillion)</p> <p>Studies indicate that when ivermectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive.</p>
Environmental risk and safety phrases:	<p>Environmentally hazardous substance, Solid, N.O.S. (ivermectin)</p> <p>Marine pollutant</p>

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :	<p><u>Product disposal:</u> To avoid disposal all attempts should be made to utilise the product completely in accordance with its registered use. Bury unusable product in an approved landfill.</p> <p><u>Container disposal:</u> Drug containers and any damaged or time-expired capsules should be disposed of safely eg. by incineration or burial in an approved landfill as free ivermectin may adversely affect fish and certain water-borne organisms. If an authorized landfill is not available, bury capsules in a disposal pit specifically set up and made for this purpose, clear of waterways and vegetation.</p>
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SECTION 14: TRANSPORT INFORMATION

Relevant information:	<p>DG Class 9 for road transport</p> <p>UN 3082</p> <p>Maximum Transport Quantity: 250 kg</p>
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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 A9463. See www.nzfsa.govt.nz/acvm for registration conditions.
HSNO and ACVM controls:	Refer to Section 3
List exposure limits:	No exposure limits have been specifically assigned to this product. Albendazole Permissible in-house exposure limit (PIEL) = 0.3mg/m

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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