



SAFETY DATA SHEET

Product Name: IVOMEK MAXIMIZER CR Capsule for Adult Sheep

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Reviewed on: 13 September 2007

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name: IVOMEK MAXIMIZER CR Capsule for Adult Sheep
Product code: A7192
Recommended use: For the treatment and control of major internal parasites, nasal bots, keds and itchmite 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: Controlled Release Capsule / Ivermectin

Product components:

<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Ivermectin	70288-86-7	3.6%
Ingredients determined to be non-hazardous		Qs

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications: 6.1C, 6.8C, 6.9B, 9.1A, 9.2B, 9.3B, 9.4A
Priority and secondary identifiers: Toxic – 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.
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.
Very toxic to terrestrial invertebrates. Apply only as directed

SECTION 4: FIRST AID MEASURES

Necessary first aid Contact the National Poisons Information Centre for further

measures:	information: phone 0800 POISON (764 766) <u>Eye contact:</u> Flush with plenty of water. Get medical attention if irritation persists. <u>Skin contact:</u> Wash with soap and water. Get medical attention if symptoms appear. <u>Inhalation:</u> No inhalation exposure is expected with normal conditions of use. <u>Ingestion:</u> If significant amount accidentally ingested, do NOT induce vomiting. Get medical attention 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:	N/A
Fire hazard properties:	If involved in a fire, toxic gases including carbon monoxide and carbon dioxide may be generated.
Regulatory requirements:	N/A
Extinguishing media and methods:	Water fog, foam, CO ₂ or dry chemical.
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 container for disposal. Use suitable protective equipment. Follow all fire prevention procedures (Section 5). Contact emergency response personnel for large spills. Keep unnecessary persons away. Ivermectin is very toxic to certain aquatic species. Avoid contact of spilled materials and runoff with soil and surface waterways. Residual surface material should be removed with towels moistened with methanol. Incinerate all spilled materials and residues at temperatures greater than 500°C. Do not flush into drains or natural waterways or areas draining into potable water supplies.
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SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:	Avoid contact with eyes. Do not ingest. Wash hands thoroughly after use.
Regulatory requirements:	N/A
Handling practices:	N/A
Approved handlers:	Not required
Conditions for safe storage:	Keep this and all drugs out of reach of children. Store below 30°C. Store in original packaging in a dry place. Protect from light.
Store site requirements:	N/A
Packaging:	Packing Group III

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:	<u>Hands/Arms:</u> 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.
Required specifications:	N/A
Further specifications:	N/A
Specific advice:	N/A

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable under normal storage.
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:	Will not occur
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Carcinogen Designation:	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.
Effects of Acute Exposure:	<u>Eye Contact:</u> Under normal conditions of use, no eye contact is expected with this formulation. Direct contact of the product mixture with eyes can cause irritation. <u>Skin Contact:</u> 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. <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. <u>Ingestion:</u> The acute oral toxicity of this formulation is unknown. 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.

Effects of Chronic Exposure:	<p>If overdosed to ivermectin, symptoms may include 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>
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SECTION 12: ENVIRONMENTAL INFORMATION

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

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :	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.
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SECTION 14: TRANSPORT INFORMATION

Relevant information:	DG Class 9 for road transport UN 3082 Maximum Transport Quantity: 250 kg Tracking not required
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No. A7192 See www.nzfsa.govt.nz/acvm for registration conditions. Approved pursuant to the HSNO Act 1996, Approval Code HSR001839. 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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