

SAFETY DATA SHEET

Product Name: IVOMEK Injection for Cattle, Sheep and Pigs

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Reviewed on: 25 September 2007

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	IVOMEK Injection for Cattle, Sheep & Pigs
Product code:	A7392
Recommended use:	For the treatment and control of internal and external parasites of cattle, sheep and pigs.
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:	25 September 2007

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization:	Multicomponent Liquid / Avermectin	
Product components:		
<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Ivermectin Comp. B1a	70288-86-7	
Comp. B1b	(mixture)	
Propylene Glycol	57-55-6	
Glycerol Formal	5464-28-8	

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.1D, 6.8B, 6.8C, 6.9B, 9.1A, 9.2C, 9.3C, 9.4A
Priority and secondary identifiers:	Harmful – keep out of reach of children Ecotoxic
Risk and safety phrases:	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. Harmful – may cause reproductive / development damage from repeated oral exposure. Keep out of reach of children. Do not handle until all safety precautions have been read and understood. 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.

Harmful to the soil environment. Apply only as directed.

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: For advice, contact the National Poisons Centre: 0800 POISON (0800 764766) or a doctor immediately.

Eye Contact: Flush thoroughly with plenty of water for at least 15 minutes. Get medical attention if irritation occurs or persists.

Skin Contact: Flush thoroughly with plenty of water and wash contact area with soap and water. Remove contaminated clothing and wash before reuse. If irritation occurs or persists, get medical attention.

Inhalation: In case of accidental overexposure, get to fresh air. If irritation occurs or persists, get medical attention.

Ingestion: Do NOT induce vomiting. Contact the National Poisons Centre.

Workplace facilities: N/A

Required instructions: N/A

Notes for medical personnel: N/A

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard: N/A

Fire hazard properties: Toxic gases including carbon monoxide and carbon dioxide may be generated.

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: 2X

Recommended protective clothing: Wear PVC protective clothing and breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures: In case of spillage wear appropriate protective clothing and prevent material from entering waterways. Absorb spills with inert material and place in waste containers. Sweep up solids without creating dust. Wash area with water and absorb with further inert material. Dispose of waste safely in accordance with local authorities.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: No special protection required under normal conditions of use

Regulatory requirements:	N/A
Handling practices:	N/A
Approved handlers:	Not required.
Conditions for safe storage:	Keep container closed when not in use. Keep this and all drugs out of the reach of children. Store bottle in carton to protect contents from light.
Store site requirements:	Stores containing equal to or more than 100L of IVOMEK Injection for Cattle, Sheep & Pigs require bunding and are subject to signage. See the Hazardous Substances Emergency Management Regulations 35-41, Identification Regulations 34 & 35 and NZS 8409 for further information.
Packaging:	Packing Group III

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:	N/A
Application in the workplace:	N/A
Exposure standards outside the workplace:	N/A
Engineering controls:	N/A
Personal protection:	No special protection required under normal conditions of use.
References:	N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:	<u>Appearance:</u> Clean, clear, pale straw-coloured sterile liquid.
Required specifications:	N/A
Further specifications:	N/A
Specific advice:	N/A

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable, protected from light
Conditions to avoid:	Avoid direct sunlight.
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:	N/A
Summaries data:	N/A
Effects of Acute Exposure:	<u>Eye Contact:</u> Under normal conditions of use, no eye contact with the solution is expected. Direct contact of the solution 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. Glycerol formula may be absorbed through the skin. <u>Inhalation:</u> Not an expected route of exposure for this formulation. <u>Ingestion:</u> 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 200 mcg/kg in a variety of species, including human. Ivermectin can be excreted in milk. If overexposed to Ivermectin, symptoms may include decreased activity, slow rate of breathing, dilation of the pupils, muscle tremors, and incoordination. Glycerol formula is practically non-toxic in animal studies.
Effect of Chronic Exposure:	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 500 mcg/kg/day and in adult rhesus monkeys there was no effect at the maximum dosage used 1.2 mg/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. Glycerol formula was well tolerated in chronic toxicity studies in rabbits, rats and dogs up to very high doses (288 mg/kg/day). However, in fetotoxicity studies in rodents the no effect level was set at 10 mg/kg/day. The equivalent figure in teratogenicity studies was 75 mg/kg/day.

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:	Ivermectin: LC50 (Daphnia Magna) = 36 ppt (parts per trillion). Ivermectin is very toxic to certain aquatic species. Avoid contact of spilled materials and runoff with soil and surface waterways.
Data organisation :	N/A
Environmental risk and safety phrases:	Environmentally hazardous substance, Liquid, N.O.S. (ivermectin) Marine pollutant

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :	Dispose of this product only by using in accordance with the label or at an approved landfill. Do NOT reuse container for any other purpose. Ensure
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container is completely empty. Recycle or burn if circumstances, especially wind direction and local authority bylaws permit. Otherwise bury in a suitable landfill.

SECTION 14: TRANSPORT INFORMATION

Relevant information:	Maximum Transport Quantity: 250 L
	DG Class 9
	UN 3082
	Tracking not required.
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No.A7392
	See www.nzfsa.govt.nz/acvm for registration conditions
	Approved pursuant to the HSNO Act 1996, Approval Code HSR002396.
	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.