

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	IVOMEK Plus Injection for Cattle
Product code:	A6481
Recommended use:	For the treatment and control of gastrointestinal nematodes, lungworms, liver fluke, eyeworms, warbles, mites and lice of beef and non-lactating dairy cattle.
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:	10 September 2007

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Multicomponent Liquid / Avermectin

Product components:

Name	CAS	Proportion
Ivermectin	70288-86-7	10g/L
Clorsulon	60200-06-8	100g/L
Glycerol Formal	5464-28-8	400g/L
Propylene Glycol	57-55-6	q.s. 100% w/v

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.1D, 6.6B, 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 – suspected of causing heritable mutations/genetic defects 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:

Contact the National Poisons Information Centre for further information: phone 0800 POISON (764 766).

Eye Contact: In case of contact, immediately flush eye with plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.

Skin Contact: Wash thoroughly with soap and water. Remove contaminated clothing and wash before reuse. Get medical attention if irritation develops.

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

Ingestion: If swallowed, 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:

Product is not self-igniting and does not present an explosion hazard.

Fire hazard properties:

Flash Point: 81°C

Carbon monoxide and carbon dioxide may be generated.

Regulatory requirements:

N/A

Extinguishing media and methods:

Use water spray or all purpose dry chemical. 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:

All exposed personnel should wear full protective clothing and self-contained breathing apparatus.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:

Absorb small spills on spill pillows or other suitable absorbing material and place in a sealed container for disposal. Dike large spills and transfer to an appropriate container for disposal. Use suitable protective equipment (Section 8). Follow all fire prevention procedures (Section 5). Contact emergency response personnel for large spills. Keep unnecessary persons away.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

Avoid contact with eyes and skin. Do not ingest. Refrain from smoking or eating when handling. Wash thoroughly after use.

Regulatory requirements:

N/A

Handling practices:

N/A

Approved handlers:

Not required

Conditions for safe storage:

Protect contents from light. Keep container closed when not in use.

	Keep this and all drugs out of reach of children.
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:	<p><u>Eye/Face</u>: Safety glasses are recommended if there is a potential for direct eye contact.</p> <p><u>Hand/Arm Protection</u>: Latex gloves or gloves of equal or greater protection are recommended.</p> <p><u>Respiratory Protection</u>: Not required if product is used according to directions.</p> <p><u>Additional Protective Equipment</u>: Protective clothing such as coveralls and/or apron.</p> <p><u>Ventilation</u>: Not required under normal conditions of use.</p>
References:	N/A

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:	<p><u>Appearance</u>: Clear, slightly yellow coloured solution.</p> <p><u>Odour/Threshold</u>: Practically odourless.</p> <p><u>Flash Point</u>: 81°C</p>
Required specifications:	N/A
Further specifications:	N/A
Specific advice:	N/A

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable when protected from light.
Conditions to avoid:	Avoid direct sunlight.
Material to avoid:	N/A
Hazardous decomposition products:	Carbon monoxide and carbon dioxide may be generated if heated to decomposition.
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><u>Eye Contact</u> : Under normal conditions of use, no eye contact with the solution is expected. Direct contact of the solution with the eyes can cause irritation. Glycerol formula is moderately irritating to the eyes. Clorsulon is a slight to moderate ocular irritant.</p> <p><u>Skin Contact</u>: Ivermectin and Clorsulon are non-irritating in animal studies. Although skin absorption of the formulation of this formulation of ivermectin has not been established, it has been shown that less than 1% of the closely related compound abamectin</p>

is absorbed through the skin of the rhesus monkeys when it is applied as emulsifiable concentrate or suspended in alcohol. Glycerol formula may be absorbed through the skin. Propylene glycol was reported to be a skin sensitizer.

Inhalation: Not an expected route of exposure for this formulation.

Ingestion: 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 other species in which the compound has been tested. It is therefore inappropriate to base human risk assessment on the response of mice. Ivermectin is used at a therapeutic dose of 200mcg/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 pupils, muscle tremors, and incoordination. Glycerol formula is practically non-toxic in animal studies.

Effects 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 500mcg/kg/day and in immature 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.

Glycerol formula was well tolerated in chronic toxicity studies in rabbits, rats and dogs up to very high doses (288mg/kg/day). However, in fetotoxicity studies in rodents the no effect level was set at 10mg/kg/day. The equivalent figure in teratogenicity studies was 75mg/kg/day.

Clorsulon is negative in several bacterial and mammalian cell mutation studies. In studies in mice, chromosome damage and bone marrow toxicity were seen at high doses.

Carcinogen Designation:

Not listed with the International Agency for Research on Cancer.

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:

Ivermectin photodegrades rapidly in the environment and is metabolized in the soil. Water solubility is limited and it binds to soil very tightly. It does not bioconcentrate in fish and is not taken up from soil into plants.

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 :

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
 Disposal must be made according to official regulations.

SECTION 14: TRANSPORT INFORMATION

Relevant information:

Maximum Transport Quantity: 250 L
 DG Class 9

Other requirements:	UN 3082 Tracking not required N/A
----------------------------	---

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No.A6481. See www.nzfsa.govt.nz/acvm for registration conditions. Approved pursuant to the HSNO Act 1996, Approval Code HSR001840. 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.
--------------------------------	--