

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	IVOMEK Injection for Cattle, Sheep & Pigs
Product code:	A007392
Recommended use:	For the treatment and control of internal and external parasites of cattle, sheep and pigs.
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City Auckland 2104 New Zealand
Telephone number:	Phone: +64 9 263 1400
Emergency telephone number:	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre: 0800 764 766 (0800 POISON) Fire Service, Ambulance: Dial 111
Date of issue:	25 September 2007
Date of review:	17 February 2022

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization:	Liquid	
Product components:		
Name	CAS	Proportion
Ivermectin	70288-86-7	10 g/L
Other		To 1 L

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	Acute toxicity (Category 4), Reproductive toxicity (Category 2), Reproductive toxicity - Effects on or via lactation (Additional category), Specific target organ toxicity – single exposure (Category 2), Specific target organ toxicity – repeated exposure (Category 2), Hazardous to the aquatic environment acute (Category 1), Hazardous to the aquatic environment chronic (Category 1), Hazardous to the terrestrial environment
Priority and secondary identifiers:	WARNING
Risk and safety phrases:	<u>Hazard Statements</u> Health Hazard – Acute toxicity (Category 4) Warning. Oral: Harmful if swallowed Warning. Dermal: Harmful if in contact with the skin Warning. Inhalation: Harmful if inhaled Health Hazard – Reproductive toxicity (Category 2) Warning. Suspected of damaging fertility or the unborn child Health Hazard – Reproductive toxicity – Effects on or via lactation (Additional category) May cause harm to breast-fed children Health Hazard - Specific target organ toxicity – single exposure (Category 2) Warning. May cause damage to organs

Health Hazard - Specific target organ toxicity – repeated exposure (Category 2)

Warning. May cause damage to organs through prolonged or repeated exposure

Environmental hazards - Hazardous to the aquatic environment acute (Category 1)

Warning. Very toxic to aquatic life

Environmental hazards - Hazardous to the aquatic environment chronic (Category 1)

Warning. Very toxic to aquatic life with long lasting effects

Environmental hazards – Hazardous to the terrestrial environment

Hazardous to soil organisms

Hazardous to terrestrial vertebrates

Hazardous to terrestrial invertebrates

Precautionary statements

Precautionary statement - General

P101 If medical advice is needed, have product container or label at hand

P102 Keep out of reach of children

P103 Read carefully and follow all instructions

Precautionary statement – Prevention

P201 Obtain special instructions before use

P202 Do not handle until all safety precautions have been read and understood

P260 Do not breathe dust/fume/gas/mist/vapours/spray

P261 Avoid breathing dust/fume/gas/mist/vapours/spray

P263 Avoid contact during pregnancy and while nursing

P264 Wash contaminated skin/eyes thoroughly after handling

P270 Do not eat, drink or smoke when using this product

P271 Use only outdoors or in a well-ventilated area

P273 Avoid release to the environment

P280 Wear protective gloves/protective clothing/eye protection/face protection

Precautionary statement – Response

P301 + P312 IF SWALLOWED: Call a POISON CENTRE/Doctor if you feel unwell

P302 + P352 IF ON SKIN: Wash with plenty of water

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing

P308+P311 IF exposed or concerned: Call a POISON CENTRE/Doctor

P308 + P313 IF exposed or concerned: Get medical advice/attention

P312 Call a POISON CENTRE/doctor if you feel unwell

P314 Get medical advice/attention if you feel unwell

P321 Specific treatment – see Section 4: First Aid Measures

P330 Rinse mouth

P362 + P364 Take off contaminated clothing and wash it before reuse

P391 Collect spillage

Precautionary statement – Storage

P405 Store locked up

Precautionary statement – Disposal

P501 Dispose of contents/container according to the label description of one or more appropriate and achievable methods for the disposal of a substance in accordance with the Hazardous Substances (Disposal) Regulations 2001. This may also include any method of disposal that must be avoided. See Section 13 for disposal details.

SECTION 4: FIRST AID MEASURES

Necessary first aid measures:	For advice, contact the National Poisons Centre: 0800 POISON (0800 764766) or a doctor immediately. <u>Eye Contact:</u> Flush thoroughly with plenty of water for at least 15 minutes. Get medical attention if irritation occurs or persists. <u>Skin Contact:</u> 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. <u>Inhalation:</u> In case of accidental overexposure, get to fresh air. If irritation occurs or persists, get medical attention. <u>Ingestion:</u> 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.
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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 100 L 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:	<p><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.</p> <p><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.</p> <p><u>Inhalation:</u> Not an expected route of exposure for this formulation.</p> <p><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.</p> <p>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.</p>
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 (<i>Daphnia Magna</i>) = 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 container is completely empty. Recycle or burn if circumstances, especially wind direction and local authority bylaws permit. Otherwise bury in a suitable landfill.
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SECTION 14: TRANSPORT INFORMATION

Relevant information:	Dangerous Goods for transport. ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Ivermectin) UN Number: 3082 Dangerous Goods Class: 9 Maximum Transport Quantity: 250 L
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No.A007392 See www.foodsafety.govt.nz for registration conditions Approved pursuant to the HSNO Act, Approval Code HSR100758 See www.epa.govt.nz for approval conditions Classified as Hazardous according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
HSNO and ACVM controls:	Refer to Section 3
List exposure limits:	N/A

SECTION 16: OTHER INFORMATION

Additional information:	For product information visit the Boehringer Ingelheim website www.boehringer-ingelheim.co.nz
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