Date of Issue: January 2011

MATERIAL SAFETY DATA SHEET:
Bomectin Injection

1. IDENTIFICATION OF CHEMICAL PRODUCT AND COMPANY

Product name
Bomectin Antiparasitic Injection for Cattle and Pigs

Other names
None allocated.

USE:
FOR ANIMAL TREATMENT ONLY
For treatment of ivermectin sensitive internal and external parasites in cattle and pigs.

Appearance
Clear, colourless ready to use sterile solution for injection.

SUPPLIER COMPANY DETAILS:
Bomac Pty Ltd

Address
15/36 Leighton Place
Hornsby NSW 2077
Australia

Telephone Number
61 (0)2 9987 4922

Emergency Number (for general information)
61 (0)2 9987 4922 (Business hours only)

Facsimile Number
61 (0)2 9987 4188

2. HAZARDS IDENTIFICATION

STATEMENT OF HAZARDOUS NATURE:
Hazardous substance, non dangerous goods according to criteria of NOHSC* Australia and ADG** Code.

Poison Schedule
S5.

R24; Toxic in contact with skin
R25; Toxic if swallowed.
R61; May cause harm to the unborn child.
R64; May cause harm to breastfed babies.

*NOHSC = National Occupational Health and Safety Commission.

**ADG= Australian Dangerous Goods code

3. COMPOSITION

INGREDIENTS:

Chemical Name	CAS No.	Content
Ivermectin	70288-86-7	10mg/mL

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

4. FIRST AID MEASURES

Swallowed:
If poisoning occurs contact a doctor or the Poisons Information Centre Ph. 13 11 26.

Eye:
Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician if irritation persists.

Skin:
Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Seek medical attention if irritation develops.

Inhaled:
Move individual to fresh air. Seek medical attention if breathing difficulty occurs.

5. FIRE FIGHTING MEASURES

FLAMMABILITY:
Non flammable.

Suitable Extinguishing Media
Use water spray, foam, powder and carbon dioxide fire extinguishers appropriate to the surrounding area. Equipment should be thoroughly decontaminated after use.

Combustion Hazards
Non combustible. Decomposition may produce toxic fumes of carbon dioxide (CO_2) and other pyrolysis products typical of burning organic material. May emit poisonous fumes.

Hazchem Code
None allocated.

6. ACCIDENTAL RELEASE MEASURES

Emergency Procedures
None applicable

Method of Containment and Clean Up Procedures
Clean up spills immediately. Absorb spills using suitable absorbing material and place in a sealed container for waste disposal. Ivermectin is very toxic to certain aquatic species. Avoid contact of spilled materials and runoff with soil and surface waterways. Do not flush into drains or natural waterways or areas draining into potable water supplies. Use suitable protective equipment. Contact emergency response personnel for large spills. Keep unnecessary persons away.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Limit all unnecessary personal contact. Avoid eye and skin contact. Do not smoke, eat or drink while handling or using the product. Observe good personal hygiene by washing hands before and after use. Wear protective clothing when risk of exposure can occur. Containers should always be kept closed in storage and stored in original labeled container. Keep out of reach of children.

Conditions for Safe Storage
Store below 30℃ (Room temperature) in a dry place and away from direct sunlight. Store in original container that is clearly labeled and free from leaks. No special ventilation is recommended under normal conditions of storage and use.

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION

National Exposure Standards
Exposure limits have not been established by NOHSC for any of the significant ingredients in this product.

The ADI for Ivermectin is set at 0.001mg/kg/day. The corresponding NOEL is set at 0.1mg/kg/day.

ADI means Acceptable Daily Intake and NOEL means no-observable-effect-level.
Values taken from Australian ADI List, Dec 2006.

IVERMECTIN:
CEL TWA: 0.02 mg/m³ [Mercke]
0.08 mg/m³ [Mercke, Sharp and Dohme]

Therapeutic doses of 0.2 mg/kg do not produce signs of toxicity in a variety of species including humans. There were no gross or histological changes seen in dogs treated with ivermectin for 3 months (no-observed-adverse-effect-level (NOAEL) = 0.5 mg/kg/day) or in monkeys treated for 2 weeks (NOAEL = 1.2 mg/kg/day). Changes in the spleen, bone marrow and kidneys were reported in rats treated for 3 months (NOAEL = 0.4 mg/kg/day). Ivermectin produced developmental toxicity in mice, rats and rabbits at or near dosage levels that were maternally toxic (NOAEL = 0.1 mg/kg/day in mice, the most sensitive species). Neonatal rats are about 20 times more susceptible to ivermectin than adult rats because the blood brain barrier is not fully developed until after birth. There has been no evidence of teratogenicity in controlled studies in pregnant cattle, swine and dogs at up to three times the clinical dose nor has breeding performance been affected in various species. The targeted clinical dosage of 0.15-0.2 mg/kg and doses in the range of 3 to 12 mg are given according to body weight. Higher dosages (0.4 mg/kg) have been given to patients with lymphatic filariasis. For treatment of onchocerciasis caused by Onchcerca volvulus, a leading cause of river blindness in tropical areas), the drug is given only once every six or twelve months. Ivermectin is metabolised in the liver and excreted almost exclusively in the faeces over a period of twelve days. The

plasma half-life in man is about 10-12 hours for ivermectin and 3 days for its metabolites. Side-effects are not considered to be due to the toxicity of ivermectin as such, but are attributed to hypersensitivity reactions resulting from the death of the microfilariae. In cases of accidental overdose with ivermectin, there have been no fatalities reported; however symptoms resemble those in animal studies. An acceptable daily dose (ADI) of 0.8 mg/day was derived using the lowest dosage given clinically to adults (which is not associated with central nervous system toxicity) and applying a 10 fold uncertainty factor to account for interindividual variability. The recommended exposure limit (0.08 mg/m^3) recommended by Mercke, Sharp and Dohme, as an 8-hour TWA, and a wipe test criteria of 0.8 mg/100 cm2 were derived from the ADI.

Biological Limit Values
No biological limit allocated.

Engineering Controls
No special ventilation controls are necessary.

Personal Protective Equipment:

Eye/face protection:	Eye protection such as protective glasses or goggles are not usually necessary when this product is being used.
Skin protection:	Wear chemical protective gloves when skin contact is likely. Wash hands or other exposed areas after handling and use.
Respiratory protection:	No special respiratory protection equipment is recommended under normal conditions of use with sufficient ventilation.
Thermal hazards:	Non flammable product. No special protective equipment is recommended.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Colourless suspension liquid.
Odour:	Mild, aromatic odour.
Boiling point:	Boils at about 100℃ at 100kPa.
Vapour pressure:	No information available.
Flash point:	Will not burn until water component is driven off.
Water solubility:	Formulation slightly soluble in water.

10. STABILITY AND REACTIVITY

Chemical stability:
Stable under normal ambient and anticipated storage conditions of temperature and pressure.

Incompatible materials:
No particular incompatibilities.

Hazardous reactions:
Not applicable.

11. TOXILOGICAL INFORMATION

ALWAYS READ AND FOLLOW THE LABEL INSTRUCTIONS AND WARNINGS

ACUTE EFFECTS

Swallowed:
Toxic effects may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 40 gram may be fatal or may produce serious damage to the health of the individual. Macrolides comprise a large group of antibiotics derived from *Streptomyces* spp. having in common a macrocyclic lactone ring to which one or more sugars are attached. They are all weak bases. The most common side effect produced by the family of macrolide antibiotics is gastrointestinal discomfort. Supra-infections may occur although these are rare. Several macrolides produced allergic sensitisation but, again, these are rare. Symptoms include watery eyes, shortness of breath, nasal congestion, choking, coughing and wheezing. Allergic skin reactions have also occurred. Exposure to at least on member of the family, erythromycin, at high concentrations, has produced reversible deafness (ototoxicity). Systemic reactions including fever, rash, and lymph-node pain or swelling have been produced by the avermectin group. Ivermectin has produced ataxia (incoordination), lethargy, bradypnea (slowed breathing), vomiting, mydriasis (dilated pupils), sedation, tremors and death in animals. The avermectin group (anthelmintics, insecticides and acaricides) mediate the transmission of gamma-butyric acid (GABA), an inhibitory neurotransmitter, in mammals thus causing paralysis. Hepatotoxic effects with transient disturbances and jaundice have resulted from the use of oleandomycin. Transient alterations in heart rate/ rhythm have also been produced by several members of the family (notably tilmicosin). Heart muscle degeneration, characterised by small areas of cell death have also been reported in animals exposed to tilmicosin. Cross-resistance is often observed between the macrolide, lincosamide and streptogramin group of antibiotics.

Eye:
The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

Skin:
Skin contact with the material may be harmful; systemic effects may result following absorption. The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

Inhaled:
Not normally a hazard due to non-volatile nature of product. The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.

CHRONIC EFFECTS

Principal routes of exposure are by accidental skin and eye contact and by inhalation of vapours especially at higher temperatures. As with any chemical product, contact with unprotected bare skin; inhalation of vapour, mist or dust in work place atmosphere; or ingestion in any form, should be avoided by observing good occupational work practice.

Animal Toxicity Data Single Exposure –

IVERMECTIN:

TOXICITY
Oral (rat) LD_{50}: 50 mg/kg **
Oral (ratling) LD_{50}: 2-3 mg/kg **
Intraperitoneal (rat) LD_{50}: 55 mg/kg **
Dermal (rat) LD_{50}: >660 mg/kg **
Oral (mouse) LD_{50}: 25 mg/kg **
Intraperitoneal (mouse) LD_{50}: 30 mg/kg **
Dermal (rabbit) LD_{50}: 406 mg/kg
Oral (dog) LD_{50}: 80 mg/kg~
Oral (monkey) LD_{50}: >24 mg/kg **
ADI: 0.8 mg/day **
*[Mercke]
** [Mercke, Sharpe and Dohme]

IRRITATION
Eye (rabbit): slight **
Skin (rabbit): non-irritating**

Metabolism

Ivermectin undergoes metabolism and is excreted mainly in the faeces. Ivermectin is little metabolised by mammals; 90% of the administered dose is excreted in the faeces and tissue residues are of the parent.

Elimination by route of exposure

Ivermectin is excreted mainly in the faeces (unchanged), less than 1% appearing in the urine and less than 2% in breast milk. In animal studies, regardless of whether Ivermectin is administered parenterally or orally, only 0.5 to 2% of the dose is excreted in urine; the remainder (about 90%) appears in the faeces.

Note: This product is a registered veterinary chemical and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

12. ECOLOGICAL INFORMATION

Ecotoxicity:
This product is very toxic to aquatic organisms.
Daphnia magna LC_{50} 48 hours = 0.025 ppb; NOEL = 0.01 ppb;
Rainbow trout LC_{50} 96 hours = 3.0 ppb;
Bluegill sunfish LC_{50} 96 hours = 4.8 ppb.

Persistence/Degradability:
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 to plants. Both aquatic and terrestrial studies confirm rapid degradation of Ivermectin in the environment and lack of accumulation and persistence.

13. DISPOSAL CONSIDERATIONS

Disposal Methods
Shake and empty contents into medicated water. Do not dispose of undiluted chemicals on site. Puncture or shred and bury empty containers in a local authority landfill. If not available bury the containers below 500mm in a disposal pit specifically marked and set up for this purpose clear of waterways, vegetation and roots. Do not allow product to contaminate waterways or sewage disposal areas. Used needles should immediately be placed in a designated and appropriately labeled "sharps" container.

14. TRANSPORT INFORMATION

UN Number
None allocated

Proper Shipping Name
None allocated

Dangerous Goods Class and Subsidiary Risk
None allocated

Packaging Group Number
None allocated

Special Precautions for User
Store below 30℃ (Room temperature) and away from d irect sunlight.

Hazchem Code
None allocated.

15. REGULATORY INFORMATION

Bomectin Antiparasitic Injection for Cattle and Pigs is classified as S5 according to the Standard for the Uniform Scheduling of Drugs & Poisons (SUSDP). All significant ingredients in this formulation may be found in the public Australian Inventory of Chemical Substances (AICS).

16. OTHER INFORMATION

Contact Point
Production Manager
Bomac Pty Ltd
Telephone: 61 (0)2 9987 4922

Australian Poisons Information Centre: 13 11 26 (24 hour service)
Police, Fire Brigade or Ambulance: 000

New Zealand Poisons Information Centre: 0800 764 766 (24 hour service)

MATERIAL SAFETY DATA SHEET:
Bomectin Injection

New Zealand Emergency Services: 111

This Material Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace.

As conditions of use are beyond the control of Bomac Pty Ltd, no legal responsibility is accepted for the use of this information.

Each user should read this MSDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products. If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.