

MATERIAL SAFETY DATA SHEET

SECTION 1 – PRODUCT IDENTIFICATION AND USE			
MANUFACTURER'S NAME:	BIMEDA-MTC ANIMAL HEALTH INC.	SUPPLIER'S NAME:	BIMEDA-MTC ANIMAL HEALTH INC.
STREET ADDRESS:	420 BEAVERDALE ROAD	STREET ADDRESS:	420 BEAVERDALE ROAD
CITY AND PROVINCE:	CAMBRIDGE, ONTARIO	CITY AND PROVINCE:	CAMBRIDGE, ONTARIO
POSTAL CODE:	N3C 2W4	POSTAL CODE:	N3C 2W4
TELEPHONE #	519-654-8000	TELEPHONE #	519-654-8000
EMERGENCY RESPONSE:	CHEMTREC	TELEPHONE #	1-800-424-9300
CHEMICAL NAME:	CHEMICAL FAMILY:	CHEMICAL FORMULA:	
PRODUCT USE: For the treatment and control of gastrointestinal nematodes, lungworms, liver fluke, eye-worms, warbles, mites and lice of beef and non-lactating dairy cattle.			
PRODUCT CODE: 1BIM009 1BIM010 1BIM011		PRODUCT SIZE: 50 mL 250 mL 500 mL	

SECTION 2 – COMPOSITION / INFORMATION ON INGREDIENTS				
INGREDIENTS	MOLECULAR FORMULA	MOLECULAR WEIGHT	CAS NUMBER	PERCENT %
Ivermectin Comp. B1a Comp. B1b (mixture)	$C_{48}H_{74}O_{14G}$ $C_{48}H_{72}O_{14}$	875 861	70288-86-7	1.0
Clorsulon	$C_8H_8C_{13}N_3O_4S_2$	380.65	60200-06-8	10.0
Propylene Glycol	$C_3H_8O_2$	76.09	57-55-6	50.0
Glycerol formal	$C_4H_8O_3$	104	5464-28-8	39.0

SECTION 3 – PHYSICAL DATA			
PHYSICAL STATE: Liquid	ODOUR AND APPEARANCE: Clear, slightly yellow coloured.	ODOUR THRESHOLD (ppm): Practically odourless.	
VAPOUR PRESSURE (mm Hg): Not established	VAPOUR DENSITY (Air = 1): Not established	EVAPORATION RATE (Ether = 1):	
BOILING POINT (DEG.C): Not established	FREEZING POINT (DEG. C): Not established	MELTING RANGE (DEGC/DEGF): Not established	
pH (100%): Not established	SPECIFIC GRAVITY (H ₂ O = 1): 1.09-1.21 (25 deg C)	SOLUBILITY IN WATER: Not established	VOLATILE COMPONENTS (% W/W): Not established

SECTION 4 – FIRE AND EXPLOSION DATA		
FLAMMABLE: IF YES, UNDER WHICH CONDITIONS:		
MEANS OF EXTINCTION: Use water spray or all purpose dry chemical.		
SPECIAL FIRE FIGHTING PROCEDURES: Fire fighters should wear self-contained breathing apparatus and full protective equipment.		
FLASHPOINT (Deg. C) AND METHOD: Not established	UPPER FLAMMABLE LIMIT (% BY VOLUME): Not established	LOWER FLAMMABLE LIMIT (% BY VOLUME): Not established
AUTOIGNITION TEMPERATURE (DEG. C): Not established	HAZARDOUS COMBUSTION PRODUCTS:	
FIRE AND EXPLOSION HAZARDS: None known	HAZARDOUS DECOMPOSITION PRODUCTS RESULTING FROM A FIRE: If involved in a fire, toxic gases including carbon monoxide and carbon dioxide may be generated.	

SECTION 5 – EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE GUIDELINES:			
COMPONENT	OSHA PERMISSIBLE EXPOSURE LIMIT (PEL)	ACGIH THRESHOLD LIMIT VALUE (TLV)	EXPOSURE CONTROL LIMIT (ECL)
Ivermectin	Not established	Not established	0.08 mg/m ³
Glycerol	Not established	Not established	Not established
Clorsulon	Not established	Not established	2.0 mg/m ³
Propylene Glycol	Not established	Not established	Not established

PERSONAL PROTECTIVE EQUIPMENT:		
GLOVES (Specify): Rubber gloves or other impervious gloves.	RESPIRATOR (Specify): Not required if product is used according to directions.	EYES (Specify): Safety goggles if direct eye contact is likely.
FOOTWEAR(Specify):	CLOTHING (Specify): Protective clothing such as coveralls and/or apron.	VENTILATION: Not required under normal conditions of use.

SECTION 6 – REACTIVITY DATA

CHEMICAL STABILITY – (IF NO, UNDER WHICH CONDITIONS?) Stable, protected from light.
INCOMPATIBILITY WITH OTHER SUBSTANCES (IF YES, WHICH ONES?) None known
REACTIVITY, AND UNDER WHAT CONDITIONS?
HAZARDOUS POLYMERIZATIONS: None known

SECTION 7 – HAZARDS IDENTIFICATION

EFFECTS OF ACUTE EXPOSURE TO MATERIAL:

EYE CONTACT: Under normal conditions of use, no eye contact with the solution is expected. Direct contact of the solution with eyes can cause irritation. Glycerol formal is moderately irritating to the eyes.

SKIN CONTACT: 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 on rhesus monkeys when it is applied as emulsifiable concentrate or suspended in alcohol. Glycerol formal 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 the other species 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 formal 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 500 mcg/kg/day and in immature 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.

Glycerol formal was well tolerated in chronic toxicity studies in rabbits, rates 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.

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 8 – PREVENTATIVE MEASURES

ENGINEERING CONTROLS:

LEAK AND SPILL 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 V). Follow all fire prevention procedures (Section IV). Contact emergency response personnel for large spills. Keep unnecessary persons away.

WASTE DISPOSAL: Residual surface material should be removed with towels moistened with methanol. Incinerate all spill material and residues at temperatures greater than 600 deg C.
Do not flush into drains or natural waterways or areas draining into potable water supplies.

STORAGE AND HANDLING REQUIREMENTS: Avoid direct sunlight.

SECTION 9 – TOXICOLOGICAL INFORMATION

Quantitative Toxicity Data: For pure Ivermectin:

Test	Species	Route	Result
LD50	Mouse	Oral	25 mg/kg
LD50`	Mouse	Intraperitoneal	30 mg/kg
LD50	Rat	Oral	50 mg/kg
LD50	Rat	Intraperitoneal	55 mg/kg
LD50	Rat (Infant)	Oral	2 to 3 mg/kg
LD50	Rat	Inhalation	Maximum attainable concentration of 5.11 mg/liter produced transient irritation of mucous membranes but no deaths or other signs of toxicity after 1 hour exposure.
LD50	Rat	Dermal	More than 660 mg/kg
LD50	Rabbit	Dermal	406 mg/kg
LD50	Dog	Oral	About 80 mg/kg
LD50	Rhesus monkey	Oral	More than 24 mg/kg

Clorsulon:

Test	Species	Route	Result
LT50	Mouse	Oral	Greater than 20 gm/kg
LD50	Rat	Oral	Greater than 20 gm/kg
Skin	Rabbit	Topical	Non-irritating
Eye	Rabbit	Direct Contact	Slight to moderate ocular irritant

Glycerol Formal:

Test	Species	Route	Result
LD50	Mouse	Oral	8.0 mg/kg
LD50	Rate (F)	Oral	9.4 g/kg
LD50	Rat (M)	Oral	10.2 g/kg
LD50	Mouse (F)	Intravenous	4.0 g/kg
LD50	Mouse (M)	Intravenous	4.8 g/kg
Skin	Rabbit	Topical	Non-irritating
Eye	Rabbit	Direct Contact	Moderately irritating

Propylene Glycol:

Test	Species	Route	Result
LD50	Rabbit	Dermal	Greater than 10 gm/kg

SECTION 10 – ECOLOGICAL INFORMATION

Environmental Fate: Ivermectin photo degrades 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. Both aquatic and terrestrial studies confirm the rapid degradation of Ivermectin in the environment and its lack of accumulation and persistence.

Environmental Effects:

Pure Ivermectin:

LC50 – (Daphnia Magna) = 0.025 ppb (very highly toxic to aquatic organisms).

Ivermectin is very toxic to certain aquatic species. Avoid contact of spilled materials and runoff with soil and surface waterways.

Product Identifier: BIMECTIN PLUS INJECTION FOR CATTLE

DIN #:

SECTION 11 – PREPARATION DATA			
Shipping Requirements: Drugs or medicines, NOI Class 70 NMFC 60000 RVMX:			
DATE:	October 27, 2004	TELEPHONE NUMBER:	519-654-8000
DATE UPDATED:	September 2007, August 2009, August 2010, May 2014		

Information for this material safety data sheet was obtained from sources considered technically accurate and reliable. While every effort has been made to ensure full disclosure of product hazards, in some cases data is not available and is so stated. Since conditions of actual product use are beyond the control of the supplier, it is assumed that user of this material has been fully trained according to the mandatory requirements of WHMIS. No warranty, expressed or implied, is made and supplier will not be liable for any losses, injuries or consequential damages which may result from the use of or reliance on any information contained in this form. If user requires independent information on ingredients in this or any other material, we recommend contact supplier.