

SAFETY DATA SHEET

According to EPA Hazardous Substances (Safety Data Sheets) Notice 2017

Section 1. Identification of the material and the supplier

Product Name: **ANIMEC SUPER
(IVERMECTIN (1%)-CLORSULON (10%) Injection -
All presentation)**

Product Use: VETERINARY; Injectable Parasiticide with Anthelmintic & Fasciolicidal Properties (for Bovine Use). For Animal Treatment Only.

Restriction of Use: For use as a veterinary medicine only

Manufacturer: Chanelle Pharmaceuticals Manufacturing Ltd.
Dublin Road, Loughrea, Co. Galway,
Rep. of Ireland

New Zealand Supplier: AHD Ltd
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New Zealand

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Hawke's Bay
NZ

Telephone: 06 873 3611

Emergency Telephone: 0800 764 766 (National Poison Centre)

Date of SDS Preparation: 27 October 2017

Section 2. Hazards Identification

This substance is hazardous according to the *Hazardous Substances (Minimum Degrees of Hazard) Notice 2017*

EPA Approval No: HSR100758

Pictograms:



Signal Word: **Warning**

HSNO Classification	Hazard Code	Hazard Statement	GHS Category
6.1D (oral)	H302	Harmful if swallowed.	Category 4
6.6B	H341	Suspected of causing genetic defects.	Category 2
6.8B	H361	Suspected of damaging fertility or the unborn child.	Category 2
6.8C	H362	May cause harm to breast-fed children.	Effects via lactation

6.9B (Repeated exposure)	H373	May cause damage to kidneys through prolonged or repeated exposure.	Category 2
9.1A	H410	Very toxic to aquatic life with long lasting effects.	Category 1
9.2D	H423	Harmful to the soil environment.	-
9.3C	H433	Harmful to terrestrial vertebrates.	-
9.4A	H441	Very toxic to terrestrial invertebrates.	-

Prevention Code	Prevention Statement
P102	Keep out of reach of children.
P103	Read label before use.
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe mist, vapours or spray.
P263	Avoid contact during pregnancy/while nursing.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P281	Use personal protective equipment as required.

Response Code	Response Statement
P101	If medical advice is needed, have product container or label at hand.
P330	Rinse mouth.
P391	Collect spillage.
P301 + P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P308 + P313	IF exposed or concerned: Get medical advice/ attention.

Storage Code	Storage Statement
None allocated	Keep all medicines stored away from children, pets and animals; Finished Product does not require any special storage conditions though it is recommended to store securely, under 30°C, dry, & well ventilated area Avoid storing in direct sunlight.

Disposal Code	Disposal Statement
P501	This product must be disposed of as a hazardous waste and disposed of in accordance with Local Authority Requirements & Regulations- Waste Products should not be disposed of untreated to drain

Section 3. Composition / Information on Hazardous Ingredients

Ingredients	Wt%	CAS NUMBER.
Ivermectin	1%	70288-86-7
Clorsulon	10%	60200-06-8
Glycerine formal	40%	4740-78-7 / 5464-28-8
Other components not contributing to the classification	Remainder	

Section 4. First Aid Measures

Routes of Exposure:

General: If unconscious, place person on their side in the recovery position; contact medical aid; give access to this SDS.

If in Eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice.

If on Skin	Wash with plenty of soap and water. Take off contaminated clothing and wash before re-use. If skin irritation occurs or persists: Get medical advice/attention.
If Swallowed	Rinse mouth. DO NOT induce vomiting. Never give anything to the mouth of an unconscious person. Allow patient to drink water. If vomiting occurs, place victim face downwards, with the head turned to the side and lower than the hips to prevent vomit entering the lungs. Get immediate medical advice/attention.
If Inhaled	Remove person to fresh air. Remove contaminated clothing and loosen remaining clothing. Allow person to assume most comfortable position and keep warm. Keep at rest until fully recovered. Get medical advice if breathing becomes difficult.

Most important symptoms and effects, both acute and delayed

Symptoms: This product contains ingredients which are known to induce gastrointestinal disturbances as well as irritate eye and respiratory tract.

Section 5. Fire Fighting Measures

Hazard Type	Non Flammable, non-combustible liquid.
Hazardous Decomposition	Possibility of Carbon Oxides (COx) & Toxic Fumes, Can react with strong oxidisers.
Suitable Extinguishing media	Dry Chemical Powder; Carbon Dioxide; Foam; Water Spray. Full Water Jet is deemed unsuitable as it may spread the flame.
Precautions for firefighters and special protective clothing	Wear self-contained respiratory protection; Wear Protective Clothing; Evacuate Area Collect contaminated Fire Fighting Media, Not to be discharged to drain.
HAZCHEM CODE	3Z

Section 6. Accidental Release Measures

Non-Emergency Personnel: No action should be taken without appropriate training, PPE, or if danger of personal risk exists. Do not walk through, touch or attempt to contain spilled material without PPE. Refer to Section 8 for PPE requirements. No Smoking. Unnecessary personnel should be removed to safe area.

Small Spills

Clear the area of all unprotected personnel. Wear appropriate protective clothing whilst cleaning up small spills (see Section 8, Personal Protection). Apply inert absorbent material such as earth, sand, universal binder or kitty litter granules to the spill. Sweep up material for disposal when absorption is complete. Clean up minor spills immediately. Affected Area may then be cleaned with Water and Detergent or Sodium Hypochlorite Solution after pick-up. Do NOT discharge spilled material to soil, sewers, waterways, surface or ground waters-Contact relevant authorities if contamination occurs.

Large Spills

Clear the area of all unprotected personnel. Wear protective clothing. Place leaking containers into salvage drums. Apply inert absorbent material such as earth, sand, universal binder or kitty litter granules to spill area. Form a barricade/bund around the spill and in front of drains or waterways in spill vicinity, using earth or other available material. Prevent entry of material into drains or water ways. Dispose of spill residues and used spill media as a hazardous waste according to Local Regulations.

Section 7. Handling and Storage

Precautions for Handling:

- Keep out of reach of children.
- Read label before use.
- Do not eat, smoke or drink while using this product.
- Keep container tightly closed when not in use.
- Keep all medicines away from children & pets; Children are particularly at risk from product and may prove harmful.
- Cats and certain breeds of Dogs can be overly susceptible to IVERMECTIN Toxicity therefore access & exposure to this product should be restricted.
- In all cases of accidental exposure through ingestion, contact medical physician immediately. Avoid contact with Skin & Eyes.
- Avoid breathing fumes, vapours or mists.
- Avoid skin contact.
- Do not contaminate water, feed, or food by storage, handling, or disposal.
- Wash hands thoroughly after handling.
- Contaminated work clothing should not be allowed out of the workplace.
- Avoid release to the environment.
- Wear protective clothing.

Precautions for Storage:

- Store away from any incompatible materials listed in Section 10.
- Store containers upright and tightly closed.
- Store below 30°C in a dry well ventilated area.
- Protect from light.
- Once opened use within 6 months.
- Keep away from food, drink, and animal food stuffs.
- Keep tightly closed.
- Emptied containers may retain product residues and therefore require rinsing before disposal.

Section 8 Exposure Controls / Personal Protection

WORKPLACE EXPOSURE STANDARDS (provided for guidance only)

Substance	TWA		STEL	
	ppm	mg/m ³	ppm	mg/m ³

No components of the formulation trigger WES limits.

Workplace Exposure Standard – Time Weighted Average (WES-TWA). *The time-weighted average exposure standard designed to protect the worker from the effects of long-term exposure.* Workplace Exposure Standard – Short-Term Exposure Limit (WESSTEL). *The 15-minute average exposure standard.* Applies to any 15- Minute period in the working day and is designed to protect the worker against adverse effects of irritation, chronic or irreversible tissue change, or narcosis that may increase the likelihood of accidents. The WES-STEL is not an alternative to the WES-TWA; both the short-term and time-weighted average exposures apply. Workplace Exposure Standards and Biological Exposure Indices JUNE 2016 8TH EDITION

Engineering Controls

No special engineering controls are required for normal use. Keep containers closed when not in use.

General safety and Hygiene Measures

Keep the work place clean. Use only clean equipment. When using do not eat, drink or smoke.

Environmental Exposure Controls: None specified; Emissions from ventilation or work processes should meet requirements of environmental protection legislation

Personal Protective Equipment



Eyes	Eye protection normally required when handling the finished product, protective eyewear (EN 166) is recommended when working with large or bulk volumes where the incidence of exposure is increased. AS/NZ1336.
Hand Protection	Gloves are required when handling bulk product for extended periods, wash hands thoroughly after handling product. The selected protective gloves have to satisfy the specifications of AS/NZS 2161:2016 or EN374.
Body	Wear suitable protective clothing Remove and wash contaminated clothing and gloves, including the inside, before re-use.
Respiratory	A (minimum) Grade Mask (EN 143) in enclosed areas recommended especially if working with bulk volumes and as a back-up to engineering controls. AS/NZS 1716 Respiratory Protective Devices and AS/NZS 1715 Selection, Use, and Maintenance, of Respiratory Protective Devices.
General	Facilities for storing or utilising this material should be equipped with an eyewash facility, safety shower and facility for washing hands and face after work.

Section 9 Physical and Chemical Properties

Appearance	Not available
Colour	Not available
Odour	Characteristic odour
Odour Threshold	Not available
pH	Not available
Boiling Point	Not available
Melting Point	Not available
Freezing Point	Not available
Flash Point	Not available
Flammability	Not available (considered not flammable)
Upper and Lower Explosive Limits	Not available
Vapour Pressure	Not available
Vapour Density	Not available
Specific Gravity	Not available
Solubility	Not available
Rainfastness	Not available
Partition Coefficient:	Not available
Auto-ignition Temperature	Not available
Decomposition Temperature	Not available
Kinematic Viscosity	Not available
Particle Characteristics	Not available
Other information	Not available

Section 10. Stability and Reactivity

Stability of Substance	This product is stable under normal conditions of use and storage.
Conditions to Avoid	Avoid extremes of light and heat.
Incompatible Materials	String oxidizing agents, Strong acids, Strong Bases, Ammonia & Peroxides.
Hazardous Decomposition Products	Non-known under recommended storage conditions.

Section 11	Toxicological Information
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Acute Effects:

Swallowed	Harmful if swallowed.
Dermal	No Available Data for Finished Product: Specific Ingredients May Cause Skin Irritation.
Inhalation	Not a foreseeable route of exposure when used as directed however may cause irritation to the respiratory tract if inhaled.
Eye	No Available Data for Finished Product: Specific Ingredients Cause Eye Irritation.
Skin/Respiratory sensitization;	No Available Data for Finished Product.

Chronic Effects:

Carcinogenicity	Finished Product Not Classified. Contains no ingredient classified as Carcinogenic. Clorsulon was classified as NOT CARCINOGENIC based on life-time animal studies.
Reproductive Toxicity	<p>Ivermectin: was teratogenic at 8.1 times Maximum Recommended Human Dose In Rats. Ivermectin was teratogenic at 4.5 times Maximum Recommended Human Dose in Mice. These events occurred at Maternotoxic Doses. No effects on Fertility Noted for Ivermectin.</p> <p>Glycerol Formal: showed evidence of Teratogenicity In Rats at high doses (300-600mg/kg 8W) Doses in a Rat Study of 75rnrlka BW indicated no teratogenicity, but had fetotoxic effects.</p> <p>Clorsulon: In a 3-generation study carried out in rats (0, 3, 30, 300 mg/kg bw orally), the reproductive performance of female rats, viability and growth of offspring in each generation were significantly affected at 300 mg/kg bw. There was no effect on the reproductive performance at the low and middle dose. A NOEL of 30 mg/kg bw/day was retained from this study. (Committee for veterinary medicine products - Clorsulon. Summary report (2) EMEA/MRL/590/99-FINAL April 1999) [EMEA]</p>
Germ Cell Mutagenicity	<p>Finished Product Not Classified.</p> <p>Clorsulon: was NEGATIVE in three standard in-vitro tests. Clorsulon was POSITIVE in two standard in-vivo tests</p>
Aspiration	Not applicable
STOT/SE	Not applicable
STOT/RE	<p>Clorsulon: Primary Organ: Renal toxicity (Kidney)</p> <p>In a 54 week oral toxicity study in rats with a 27 week interim necropsy, groups of 60 albino rats (30 animals per sex and dose) received clorsulon by gavage at doses of 0 (0.5% aqueous methylcellulose), 0.2, 2 and 20 mg/kg bw/day. At interim sacrifice (10 animals per sex per dose), hyperplasia of the urinary bladder was reported in 4 and 7 males treated at 2 and 20 mg/kg bw, respectively. In females, this effects was only reported in 2 animals treated at the highest dose. At terminal sacrifice this finding was not so clear with 0 male and 1 female in the 2 mg/kg group, and 8 males and 2 females of the highest dose group showing urinary bladder hyperplasia. An increase in incidence and concentration of triplate phosphate crystals primarily in males, which became more proinant in week 51 was also described in the two highest dose groups. At the lowest dose, 0.2 mg/kg bw/day, only a significant increase of pH in</p>

	urine of males was reported. In absence of hyperplasia of the urinary bladder, of histopathological effects in the kidney and of triplate phosphate crystals, this dose of 0.2 mg/kg bw/day was retained as a LOEL (Committee for veterinary medicine products - Clorsulon. Summary report (2) EMEA/MRL/590/99-FINAL April 1999) [EMEA].
Other	Not applicable

Acute Effects

Ingestion: Acute oral LD₅₀ = 1318
Dermal: Acute dermal LD50 rabbit >5000 mg/kg
Inhalation: Acute inhalation LC50 rat >5mg/l

Supplementary Information:

For the purposes of this SOS, the Acute Toxicity Estimate (ATE) for the finished product is estimated using HSNO mixture rules with an LD₅₀(oral, rat) of 11.6 mg/kg for Ivermectin [CCID Data].

Section 12. Ecotoxicological Information

HSNO Classes: 9.1A = Very ecotoxic in the aquatic environment.
9.2D Harmful to the soil environment.
9.3C Harmful to terrestrial vertebrates.
9.4A Very toxic to terrestrial invertebrates.

Ingredient	LC50	Species	Result
IVERMECTIN	Fish	Trout	3.0 µg/L
		Bluegill Sun Fish	4.8 µg/L
	Crustacean	Water Flea	0.025 µg/L
	Soil	Dung Beetle Larvae	9.2A
	Terrestrial Vertebrates	Mouse	11.6 mg/kg bw
	Bee	Bee	0.002µg/bee
CLORSULON	Crustacean	Water Flea	356 mg/l
GLYCERIN FORMAL	n/a	n/a	No data available

Persistence and degradability	No data available
Bioaccumulation	No data available
Mobility in Soil	No data available
Other adverse effects	No data available

Do not allow to enter waterways.

Section 13. Disposal Considerations

Disposal Methods:

Normal disposal of product is through use as directed on the product label.
Must be sent for special treatment in accordance with local authority regulations.
Dispose of surplus and non-recyclable products via a licensed waste disposal contractor.

Precautions:

Ensure waste containers containing unwanted or recovered product or contaminated spill media are labelled "Hazardous Waste – Ecotoxic". If triple rinsing container, add rinsate to waste container for disposal.

Methods to avoid: Do not allow to enter waterways.

Section 14	Transport Information
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This product is classified as a Dangerous Good for transport in NZ ; NZS 5433:2012

Road and Rail Transport

UN No:	3082
Class-primary	9
Packing Group	PGIII
Proper Shipping Name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.(Ivermectin)

Air Transport

UN No:	3082
Class-primary	9
Packing Group	PGIII
Proper Shipping Name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.(Ivermectin)

Marine Transport

UN No:	3082
Class-primary	9
Packing Group	PGIII
Proper Shipping Name:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.(Ivermectin)

Marine Pollutant	Yes
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Section 15	Regulatory Information
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EPA Approval Code: HSR100758

EPA Groups Standard: Veterinary Medicines (Non-dispersive closed System Application) Group Standard 2012

HSNO Classification: 6.1D (oral), 6.6B, 6.8B, 6.8C, 6.9B, 9.1A, 9.2D, 9.3C, 9.4A

HSNO Controls	Trigger Quantity
Approved/Certified Handler	Not required
Location Certificate	Not required
Tracking Trigger Quantities	Not required
Signage Trigger Quantities	100L(9.1A)
Emergency Response Plan	100L(9.1A)
Secondary Containment	100L(9.1A)
Restriction of Use	Veterinary Medicine. For Animal Treatment Only.

Section 16	Other Information
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Glossary

EC ₅₀	Median effective concentration.
EEL	Environmental Exposure Limit.
EPA	Environmental Protection Authority
HSNO	Hazardous Substances and New Organisms.
LC ₅₀	Lethal concentration that will kill 50% of the test organisms

LD ₅₀	inhaling or ingesting it.
LEL	Lethal dose to kill 50% of test animals/organisms.
OSHA	Lower explosive level.
TEL	American Occupational Safety and Health Administration.
TLV	Tolerable Exposure Limit.
UEL	Threshold Limit Value-an exposure limit set by responsible authority.
WES	Upper Explosive Level Workplace Exposure Limit

1. HSNO Hazardous Substances (Safety Data Sheets) Notice 2017

Disclaimer

This document has been prepared by TCC (NZ) Ltd and serves as the suppliers Safety Data Sheet ('SDS'). It is based on information concerning the product which has been provided to TCC (NZ) Ltd or obtained from third party sources and is believed to represent the current state of knowledge as to the appropriate safety and handling precautions for the product at the time of issue. Further clarification regarding any aspect of the product should be obtained directly from the manufacturer. While TCC (NZ) have taken all due care to include accurate and up-to-date information in this SDS, it does not provide any warranty as to accuracy or completeness. As far as lawfully possible, TCC (NZ) Ltd accept no liability for any loss, injury or damage (including consequential loss) which may be suffered or incurred by any person as a consequence of their reliance on the information contained in this SDS

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Please contact the New Zealand distributor, AHD Ltd, if further information is required.

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