SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

GHS Product identifier:	Ultramax Equine Liquid Tapewormer Broad Spectrum Wormer and Boticide for Horses
Other means of identification:	Ultramax Equine Liquid
Recommended use of the product:	For the treatment and control of tapeworm, large strongyles, hairwoms, pinworms, roundworms (ascarids), intestinal threadworms, large mouthed stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis in horses.
Supplier's Details:	Pharmachem Australia Pty Ltd Unit 6, 70 Fison Ave West Eagle Farm QLD 4009 Telephone: (07) 3868 0333
Emergency phone number:	**13 11 26 (Poisons Information Hotline)**

SECTION 2 HAZARDS IDENTIFICATION

Classification of Product:

This product is classified as a health hazard and an environmental hazard in accordance with the following classification criteria of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition.

Hazard statements:

Health hazards:	Harmful if swallowed, may damage the unborn child, may cause harm to breast-fed children.
Environmental hazard:	Very toxic to aquatic life

Health hazards:

Acute toxicity, oral: Category 4

GHS label elements, including precautionary statements:

Pictogram:

Signal word: Warning

Hazard statements: Harmful if swallowed

Precautionary statements:

Prevention: Keep out of reach of children
Do not eat drink or smoke when using this product
Wash hands thoroughly after handling

Response: If swallowed, call a Poisons Information Centre or doctor if you feel unwell
Rinse mouth

Reproductive Toxicity: Category 2

GHS label elements, including precautionary statements:

Pictogram:

Signal word: Danger
Hazard statement: May damage the unborn child
Precautionary statements:
Prevention: Keep out of reach of children
Do not eat drink or smoke when using this product
Response: Wash hands thoroughly after handling

Reproductive toxicity – Additional category for effects on or via lactation:
GHS label elements, including precautionary statements:
Pictogram: Not required
Signal word: Not required
Hazard statement: May cause harm to breast-fed children
Precautionary statements:
Prevention: Keep out of reach of children
Do not eat drink or smoke when using this product
Response: Wash hands thoroughly after handling

Other Health Hazards: None known

Environmental hazard:
Acute aquatic toxicity Category 1
GHS label elements, including precautionary statements:
Pictogram:

Signal word: Warning
Hazard statements: Very toxic to aquatic life
Precautionary statements:
Prevention: Read label before use.
Avoid release to the environment.
Response: Collect spillage

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Cas No.	Proportion
Praziquantel	55268-74-1	75 g/L
Ivermectin	70288-86-7	10 g/L
Non-hazardous, proprietary formulating ingredients		QS 1L

SECTION 4 FIRST AID MEASURES

The following First Aid directions have been set by the Australian Pesticides and Veterinary Medicines Authority (APVMA) on the basis of advice from the Office of Chemical Safety (OCS) of the Commonwealth Department of Health as part of the registration process for this product:

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26, New Zealand 0800 764 766.

However, the following additional information is provided for assistance in emergency circumstances while implementing the first aid directions above.

Ingestion:	Do not induce vomiting as aspiration of the product might occur. Drink large amounts of water.
Eye:	Flush with copious quantities of water for at least 15 minutes. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin:	Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and wash with soap if available).
Inhaled:	If fumes or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary.
Note to doctor:	Treat symptomatically.

SECTION 5 FIRE FIGHTING MEASURES

Suitable extinguishing media:	Foam, dry chemical, carbon dioxide and water fog or spray.
Hazards from combustion products:	May emit toxic fumes.
Special protective precautions and equipment for fire fighters:	Use precautions and equipment suitable for the surrounding fire.
Hazchem Code:	None allocated

SECTION 6 ACCIDENTAL RELEASE MEASURES

Emergency procedures:
Do not allow spilled material or contaminated water or clean up material to enter waterways. Surfaces coated with spilled material are slippery. Contain spill using inert absorbent material. Collect and seal contained, absorbed material in specifically labelled chemical waste containers for disposal.

Methods and materials for containment and clean up
Use absorbent material such as soil, sand or vermiculite. Wash area down with detergent and excess water. Do not allow wash water to enter sewers, drains or waterways. Contain wash water as for spilled material.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling:
The following Safety Directions have been set by the APVMA as part of the registration process on the basis of advice from the OCS, Office of Health Protection, Department of Health:

Poisonous if swallowed. May irritate the eyes. Avoid contact with eyes. Wash hands after use.

Conditions for safe storage, including any incompatibilities:
The following storage directions have been approved by the APVMA as part of the registration process and are required to appear on labelling:

Store below 30ºC (Room Temperature). Do not freeze. Store bottle in carton to protect from light.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

National exposure standards:	None set
Biological limit values:	None set
Engineering controls:	Use with adequate ventilation
Personal protective equipment:	Safety glasses and gloves may be worn.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White, milky liquid
S.G.	1.05 approx.
pH	7 approx.
Viscosity	100 – 300 cp

SECTION 10 STABILITY AND REACTIVITY

Chemical stability:	Stable
Conditions to avoid:	Keep away from heat, flame and incompatibles.
Incompatible materials:	Strong oxidising agents and bases
Hazardous decomposition products:	Oxides of nitrogen, carbon dioxide and carbon monoxide may be produced under fire conditions.
Hazardous reactions:	Hazardous polymerisation will not occur

SECTION 11 TOXICOLOGICAL INFORMATION

Routes of Exposure:
Exposure to Ultramax Equine Liquid can occur through ingestion and eye or skin contact. The major route of hazardous exposure is expected to be ingestion. There are no toxicology data available for Ultramax Equine Liquid. Information has been provided for ivermectin and praziquantel.

Signs and symptoms of exposure:

Toxic if swallowed. Pure ivermectin is considered highly toxic in acute animal studies. Symptoms noted for overexposure to ivermectin included decreased activity, slow rate of breathing, dilation of the pupils, muscle tremors, and lack of coordination. In humans, no toxic effects have been noted at doses up to 200µg/kg.

Summary of Toxicology:

Ivermectin:

Ivermectin is responsible for the major toxic effects of Ultramax Equine Liquid. In mammals, acute toxic effects derived from this chemical are central-nervous disorders, such as tremor, depression, ataxia, paresis, paralysis, depending on the test species and the applied dose.

Great differences in sensitivities to ivermectin are observed amongst various species; rodents, especially mice, show an increased sensitivity to the acute toxicity of ivermectin, whereas primates including humans possess a relatively lower degree. Therapeutic doses are usually well tolerated in all species. Subpopulations with a particularly high sensitivity have been identified in dogs (eg collies).

Teratogenic effects in laboratory animals occur only at maternotoxic doses. Studies on mutagenicity and carcinogenicity (with abamectin) are negative.

Praziquatel:

After oral administration praziquantel is quantitatively and rapidly absorbed, metabolized and excreted as a variety of metabolites predominantly via the kidneys. The acute toxicity in rats, mice, rabbits and dogs is very low. Rats tolerated by oral administration doses of up to 1000 mg/kg repeated daily for four weeks, and dogs up to 180 mg/kg for 13 weeks without any organ damage. Praziquantel did not disturb reproduction in rats (up to F2-generation), nor did it reveal teratogenic effects in mice, rats and rabbits. In extensive mutagenicity trials performed by different laboratories worldwide, in a variety of test systems, no induction of point mutations, gene conversion, DNA-repair, sister chromatid exchanges (SCEs), or X-linked recessive lethals were detected.

Acute Toxicity

Praziquantel:

LD_{50} (Oral):

Mouse	2454 mg/kg
Rat	2840 mg/kg
Rabbit	1050 mg/kg
Dog	200 mg/kg

LD_{50} (Intraperitoneal):

Mouse	376 mg/kg
Rat	586 mg/kg

LD_{50} (Subcutaneous):

Mouse	7172 mg/kg
Rat	>16000 mg/kg

LD_{50} (Intramuscular

Mouse	>2000 mg/kg
Rat	>2000 mg/kg

Ivermectin

LD_{50} (Oral):

Rat	51.8 mg/kg
Ratling	2- 3 mg/kg
Mouse	25 mg/kg
Dog	80 mg/kg
Monkey	>24 mg/kg

LD_{50} (Intraperitoneal):

Mouse	30 mg/kg
Rat	55 mg/kg

LD_{50} (Dermal)

Rabbit	406 mg/kg
Rat	>660 mg/kg

Skin:

Rabbit	Slightly irritating.

Eye:

Rabbit	Slight

SECTION 12 ECOLOGICAL INFORMATION

This product has been assessed by the APVMA in relation to its environmental affects and the APVMA has determined that the following statement is appropriate for the protection of wildlife, fish, crustaceans and the environment:
Ivermectin is extremely toxic to aquatic species. Do not contaminate dams, rivers, streams or other waterways with the chemical or used container.

A selection of ecological data on the active constituents is provided below:

Praziquantel:

Ecotoxicology:

Fish

LC_0 (96 h):	Zebra barbel (*Brachydanio rerio*)	31.6 mg/l
LC_{100} (96 h):	Zebra barbel (*Brachydanio rerio*)	100 mg/l

Daphnia

EC_{50} (48 h):	35 mg/l
EC_{100} (48 h):	100 mg/l

Bacterial toxicity

EC_{50}:	>10000 mg/l; activated sludge

Ivermectin:
Ecotoxicology:

Fish		
LC_{50} (96 h):	Rainbow trout (*Salmo gairdneri*)	0.025 ppb
	Bluegill sunfish (*Lepomis macrochirus*)	4.8 ppb
Daphnia		
Water flea (*Daphnia magna*)	3.0 ppb	

Environmental Fate:

Ivermectin photodegrades rapidly in the environment and is metabolised in soil. Water solubility is limited, and it binds tightly to soil.

Ivermectin does not bioconcentrate in fish and is not taken up from soil by plants. Both aquatic and terrestrial studies confirm the rapid degradation of ivermectin in the environment and its lack of accumulation and persistence.

SECTION 13 DISPOSAL CONSIDERATIONS

Disposal methods and containers:
The following Disposal Directions for containers have been approved by the APVMA as part of the product registration process:
Dispose of empty container by wrapping with paper and putting in garbage.

In addition, do not burn empty containers or unused product. Unused product may be disposed of in local municipal landfill.

Special precautions for landfill or incineration:
Seek advice from local government authority before disposing of unused product in municipal landfill.

SECTION 14 TRANSPORT INFORMATION

This product is not defined as Dangerous Goods by the Australian Code for the Transport of Dangerous Goods by Road and Rail and is therefore not regulated under transport legislation in Australia

SECTION 15 REGULATORY INFORMATION

This product has been registered by the APVMA (APVMA Approval No.: 64084/0410). In granting registration to any product, the APVMA has exercised its legislative responsibility to ensure that the product is suitably formulated and properly labelled and, when used according to instructions is:

- safe to the host, the user, consumers and the environment;
- efficacious (that is, the product does the job it claims it shall do); and
- not unduly prejudicial to trade.

The APVMA uses the services of a number of Australian and State government agencies as advisers to help with some of these evaluations of applications for registration of agricultural and veterinary chemical products. These include:

- the Office of Chemical Safety (OCS) of the Commonwealth Department of Health which:
  - evaluates and reports on toxicology and metabolism studies; proposes first aid and safety directions; determines poison schedule classifications; and establishes acceptable daily intakes (ADIs) and acute reference doses (ARfD); and
  - evaluates the occupational health and safety aspects of an application and recommends safety directions and occupational controls on use and advises on a Safety Data Sheet (SDS);
- the Commonwealth Department of Agriculture, Water and the Environment which evaluates environmental data and recommends appropriate use controls and instructions for the product that will protect the environment; and

- State and Territory departments responsible for agricultural and primary industries which evaluate and reports on efficacy and target crop or animal safety data for new agricultural chemicals and new uses of registered products. In some cases, the APVMA contracts this work out to other agencies such as universities, the CSIRO or to other experts.

Praziquantel is listed in the Australian Inventory of Chemical Substances (AICS) administered under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), however agricultural and therapeutic uses are excluded from assessment by NICNAS under the ICNA Act—see Excluded (non-industrial) use chemicals on AICS at:
https://www.nicnas.gov.au/chemical-information/imap-assessments/how-chemicals-are-assessed/excluded-non-industrial-use-chemicals-on-aics.

Ivermectin is not listed in the AICS.

Ivermectin as it is presented in this product appears in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) and praziquantel is not scheduled for animal preparations.

SECTION 16 OTHER INFORMATION

References:

1. FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals, (as updated), APVMA (Australian Pesticides and Veterinary Medicines Authority), https://apvma.gov.au/node/26586
2. Code of Practice – Preparation of safety data sheets for hazardous chemicals, Safe Work Australia, May 2018
3. AICS (Australian Inventory of Chemical Substances) (as updated), NICNAS (National Industrial Chemicals Notification and Assessment Scheme), https://www.nicnas.gov.au/chemical-inventory
4. APVMA Registrations and Permits, https://apvma.gov.au/node/1060
5. ADI [Acceptable Daily Intake] List (as updated), Commonwealth Department of Health, TGA (Therapeutic Goods Administration)
6. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code), Edition 7.6, 2018
7. SUSMP (Standard for the Uniform Scheduling of Medicines and Poisons) (as updated), Chemicals and Medicines Scheduling Secretariat (MD122), Scheduling and Committee Governance, TGA, Commonwealth Department of Health
8. Hazardous Chemical Information System (HCIS), Safework Australia (as updated)
9. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition, United Nations, New York and Geneva, 2019
10. NIOSH Pocket Guide to Chemical Hazards
11. Chemical Classification and Information Database (CCID) (as updated), New Zealand Environmental Protection Authority, http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx
12. National Institutes of Health (NIH), National Center for Biotechnology Information, Pubchem database, https://pubchem.ncbi.nlm.nih.gov/compound/Ivermectin

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