

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, hairworms, pinworms, roundworms (ascarids), intestinal threadworms, large mouthed stomach worms, bots, lungworms, summer sores and cutaneous onchocerciasis in horses.
Supplier's Details: Pharmachem
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Eagle Farm QLD 4009
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Contact Person: Mr Gray Boston
Emergency phone number: (07) 3630 1654

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), Third Revised Edition.

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:

The material may cause skin irritation after prolonged or repeated exposure and may produce on contact, skin redness, swelling, the production of vesicles, scaling and thickening of the skin.

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 Office of Chemical Safety (OCS) of the Commonwealth Department of Health and Aging as part of the registration process applied by the Australian Pesticides and Veterinary Medicines Authority (APVMA):

If poisoning occurs, contact a doctor or Poisons Information Centre. Telephone 131126. (*FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals*)

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:
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.

The following Safety Directions have been set by the Office of Chemical Safety, Office of Health Protection, Department of Health and Ageing in the *FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals*
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 30°C (Room Temperature). Do not freeze. Store bottle in carton to protect from light.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

National exposure standards: None allocated

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

PHARMACHEM

Date of Issue: May 2016

MATERIAL SAFETY DATA SHEET

ULTRAMAX EQUINE LIQUID

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| | |
|--------------|--------------|
| S.G. | 1.05 approx. |
| pH | 7 approx. |
| Viscosity | 100 – 300 cp |
| Ivermectin | 10 g/L |
| Praziquantel | 75 g/L |

SECTION 10 STABILITY AND REACTIVITY

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|-----------------------------------|--|
| 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.

Praziquantel:

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:

LD₅₀ (Oral):

| | |
|--------|------------|
| Mouse | 2454 mg/kg |
| Rat | 2840 mg/kg |
| Rabbit | 1050 mg/kg |

| | | |
|-------------------------------------|-------|--------------|
| LD ₅₀ (Intraperitoneal): | Dog | 200 mg/kg |
| | 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 (<i>Brachydanio rerio</i>) | 31.6 mg/l |
| LC ₁₀₀ (96 h): | Zebra barbel (<i>Brachydanio rerio</i>) | 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 (<i>Salmo gairdneri</i>) | 0.025 ppb |
| | Bluegill sunfish (<i>Lepomis macrochirus</i>) | 4.8 ppb |

Daphnia

| | |
|-------------------------------------|---------|
| Water flea (<i>Daphnia magna</i>) | 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:

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 and Ageing 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 Material Safety Data Sheet (MSDS);
- the Commonwealth Department of the Environment and Heritage (DEH) 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.

Although all ingredients appear in the Australian Inventory of Chemical Substances (AICS), they have not been assessed by NICNAS (National Industrial Chemicals Notification and Assessment Scheme)

The product is scheduled in Schedule 5 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

SECTION 16 OTHER INFORMATION

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|---------------------|---------------|
| MSDS version: | 2 |
| Date of Revision: | May 2016 |
| Update of sections: | Update to GHS |

CONTACT POINT

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References:

1. FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals, (as updated)
2. Approved Criteria For Classifying Hazardous Substances, NOHSC:1008 (2004)
3. National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC:2011]
4. AICS (Australian Inventory of Chemical Substances), Safework Australia
5. APVMA Manual of Requirements and Guidelines for Agricultural Chemicals, Version 4.1, (as updated)
6. ADI [Acceptable Daily Intake] List, Commonwealth Department of Health & Aged Care, TGA, (as updated)
7. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) 7th Edition
8. The Poisons Standard (as updated), National Drugs and Poisons Schedule Committee
9. Hazardous Substances Information System, Safework Australia (as updated)
10. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Third Revised Edition, United Nations, New York and Geneva, 2009
11. NIOSH Pocket Guide to Chemical Hazards
12. Chemical Classification and Information Database (CCID) (as updated), New Zealand Environmental Protection Authority, <http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx>

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