

SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER

GHS Product identifier: Nuheart Soluble Monthly Heartworm Tablets for Large Dogs 23kg–45kg
 Nuheart Soluble Monthly Heartworm Tablets for Medium Dogs 11kg–23kg
 Nuheart Soluble Monthly Heartworm Tablets for Small Dogs up to 11kg

Other means of identification: Nuheart Tablets

Recommended use of the product and restrictions on use: For the prevention of heartworm development in dogs.

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 in accordance with the classification criteria of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition.

Health hazard:
 Acute toxicity, oral Category 5

GHS label elements, including precautionary statements:
 Pictogram: Not required
 Signal word: Warning
 Hazard statements: May be harmful if swallowed
 Precautionary statements:
 Prevention: Keep out of reach of children
 Wear suitable protective clothing and gloves
 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

SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Cas No.	Proportion
Ivermectin	70288-86-7	
Inert tablet base	N/A	<0.15% to
100%		

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 Aged Care as part of the assessment of these products for registration by the Australian Pesticides and Veterinary Medicines Authority (APVMA):

If poisoning occurs contact a doctor or Poison Information Centre (Telephone Australia – 13 11 26; New Zealand – 0800 764 766).

However, the following information is also provided to assist in emergencies while implementing the First Aid directions above:

Ingestion:	Do not induce vomiting. Give water or milk to drink.
Eyes:	Irrigate with copious quantities of water for 15 minutes.
Skin:	(Exposure to tablet dust) Wash affected parts with soap and water.
Inhaled:	(Exposure to tablet dust) Remove effected person to a well-ventilated area with fresh air

Advice to Doctor: Treat symptomatically

SECTION 5 FIRE FIGHTING MEASURES

Products are in tablet form and are considered to be non-combustible.

Suitable extinguishing media:	Use media suitable for surrounding fire
Hazards from combustion products:	None known
Special protective precautions and equipment for fire fighters:	Use precautions and equipment suitable for surrounding fire

SECTION 6 ACCIDENTAL RELEASE MEASURES

These products are blister packed in cards of 6 tablets and are not expected to pose an emergency spill situation. Where tablets in bulk are involved e.g., prior to blister packing, the following information is applicable.

Emergency procedures:

Minimise dust generation. Sweep or vacuum up spilled material, collect and seal in drums for disposal.

Methods and materials for containment and clean up:

Wash area down with detergent and excess water. Do not allow run-off to enter drains, sewers or waterways.

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling:

The following Safety Directions have been recommended by the Office of Chemical Safety (OCS) and set by the APVMA:

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

Conditions for safe storage, including any incompatibilities:

The following storage directions have been approved for these products by the APVMA:

Store in the tightly closed original container below 30°C (Room Temperature). 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. Avoid dust generation.

Personal protective equipment:
contact

None required. Rubber gloves may be used to prevent with the tablets.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Nuheart Soluble Monthly Heartworm Tablets for Medium Dogs 11kg–23kg:	Green, biconvex tablet
Nuheart Soluble Monthly Heartworm Tablets for Small Dogs up to 11kg:	Pink, biconvex tablet
Nuheart Soluble Monthly Heartworm Tablets for Large Dogs 23kg–45kg:	Blue, biconvex tablet

Tablet Size:

Diameter:	8 mm
Thickness:	3.5 mm
Weight:	200 mg

Solubility: Soluble in water

SECTION 10 STABILITY AND REACTIVITY

Chemical stability:	Stable
Conditions to avoid:	None known
Incompatible materials:	None known
Hazardous decomposition products	None known
Hazardous reactions:	Hazardous polymerisation will not occur

SECTION 11 TOXICOLOGICAL INFORMATION

Routes of Exposure:

Exposure to Nuheart Tablets may occur through ingestion and skin contact. These are considered to be the most likely routes of exposure. There are no toxicology data available for Nuheart Tablets. Information has been provided for ivermectin.

Signs and symptoms of exposure to ivermectin:

Symptoms of ivermectin poisoning can include dilated pupils, lack of coordination, drowsiness, slow breathing, tremors, vomiting, anorexia, muscle tremors, headache and dizziness.

Summary of Toxicology:

Ivermectin is believed to bind to glutamate-gated chloride ion channels; avoid drugs that also interact with other ligand-gated chloride channels, including those which enhance GABA activity in patients with potentially toxic ivermectin exposure (e.g., barbiturates, benzodiazepines, valproic acid). Reproductive toxicant in rabbits and mice.

Acute toxicity (ivermectin):

LD ₅₀ oral (mouse):	25 mg/kg - 29.5 mg/kg
LD ₅₀ Oral (dog):	~ 80 mg/kg
LD ₅₀ Oral (rat):	50 mg/kg
LD ₅₀ Dermal (rabbit):	406 mg/kg
LC ₅₀ /4h Inhalative (rat):	5.11 mg/l

SECTION 12 ECOLOGICAL INFORMATION

Nuheart tablets are blister packed in cards of 6 tablets and are not expected to pose an environmental exposure hazard. However, where tablets in bulk are involved e.g., prior to blister packing, the following information is applicable.

No ecological information is available at this time for Nuheart Tablets. The following Information applies to the ivermectin active ingredient.

Environmental fate:

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 into plants. It does not bioaccumulate.

Ecotoxicity:

Toxicity to fish:

LC50 = 0.3 µg/L - Rainbow Trout - very toxic to fish.

Toxicity to aquatic invertebrates:

LC50 48 hr = 0.025 µg/L (*Daphnia magna*) - very toxic to Daphnia.

In the light of the above ecotoxicity values for ivermectin, the APVMA requires the following statement on the label in relation to protection of the environment:

'PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND THE ENVIRONMENT: Ivermectin is very toxic to aquatic life. Do not contaminate dams, rivers, streams or other waterways with the chemical or used container.'

SECTION 13 DISPOSAL CONSIDERATIONS

Disposal methods and containers:

The APVMA has approved the following disposal directions for containers as part of the assessment of the products for registration:

Do not burn unused product or containers. Dispose of empty pack by wrapping with paper and putting in garbage.

Special precautions for landfill:

Contact local authority before disposing of unused product in local authority landfill.

SECTION 14 TRANSPORT INFORMATION

These products are not dangerous goods under the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) and are not regulated by specific transport legislation in Australia.

SECTION 15 REGULATORY INFORMATION

Nuheart products have been registered by the APVMA as follows:

Nuheart Soluble Monthly Heartworm Tablets for Medium Dogs 11kg–23kg:	55697
Nuheart Soluble Monthly Heartworm Tablets for Small Dogs up to 11kg:	55698
Nuheart Soluble Monthly Heartworm Tablets for Large Dogs 23kg–45kg:	55696

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 Aged Care 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 Climate Change, Energy, the Environment and Water 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 in the context of the Australian Industrial Chemicals Introduction Scheme (AICIS).

These products have been placed in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) published by the Commonwealth Department of Health and Aged Care.

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, <https://www.safeworkaustralia.gov.au/doc/model-code-practice-preparation-safety-data-sheets-hazardous-chemicals>
3. Australian Inventory of Industrial Chemicals (as updated), AICIS (Australian industrial Chemicals Introduction Scheme), Australian Government Department of Health, <https://www.industrialchemicals.gov.au/search-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), <https://apvma.gov.au/sites/default/files/publication/74511-acceptable-daily-intakes-adi-for-agricultural-and-veterinary-chemicals-used-in-food-producing-crops-or-animals-edition-4-2020.pdf>
6. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code), Edition 7.7, 2020, https://www.ntc.gov.au/sites/default/files/assets/files/ADG%20Code%207.7_0.pdf
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, <https://www.tga.gov.au/publication/poisons-standard-susmp>
8. Hazardous Chemical Information System (HCIS), Safework Australia (as updated), <http://hcis.safeworkaustralia.gov.au/>
9. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Eighth Revised Edition, United Nations, New York and Geneva, 2019, <https://unece.org/ghs-rev8-2019>
10. NIOSH Pocket Guide to Chemical Hazards, <https://www.cdc.gov/niosh/npg/default.html>
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>

All information contained in this Safety Data Sheet is as accurate and up to date as possible. Since Pharmachem cannot anticipate or control the conditions under which this information may be used, each user should review the information in the specific context of the intended application. Pharmachem will not be responsible for damages of any nature resulting from use of or reliance upon the information. No expressed or implied warranties are given other than those implied as mandatory by Commonwealth State or Territory legislation.