

SAFETY DATA SHEET



Page 1 of 9

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: ProHeart® Tablets

Trade Name: ProHeart®
Chemical Family: Macrocyclic lactone

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as anti-worm agent (anthelmintic)
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Australia Pty Ltd
ABN 94 156 476 425
Level 6, 5 Rider Boulevard Rhodes
NSW 2138 AUSTRALIA
(02) 8876 0444

Emergency Phone: 1800 814 883 (all hours)
Police and Fire Brigade: 000
NSW Poisons Information Centre: 13 11 26

Product Support/Technical Services Phone: 1800 814 883
Contact E-Mail: australia.animalhealth@zoetis.com

2. HAZARDS IDENTIFICATION

Appearance: Tablet

Classification of the Substance or Mixture

GHS - Classification

Acute aquatic toxicity: Category 3
Chronic aquatic toxicity: Category 3

Label Elements

Hazard Statements: H412 - Harmful to aquatic life with long lasting effects

Precautionary Statements: P273 - Avoid release to the environment
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Short Term: May cause eye irritation Ingestion of large amounts may cause central nervous system effects.
Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

SAFETY DATA SHEET

Material Name: ProHeart® Tablets

Page 2 of 9

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number			GHS Classification	%
Microcrystalline cellulose	9004-34-6			Not Listed	25
Magnesium stearate	557-04-0			Not Listed	1
Silica colloidal, Ph. Eur.	112945-52-5			Not Listed	0.1
Moxidectin	113507-06-5			Acute Tox.3 (H301) Eye Irrit. 2A (H319) Skin Irrit 3 (H316) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	0.02

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

SAFETY DATA SHEET

Material Name: ProHeart® Tablets

Page 3 of 9

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³
Vietnam OEL - TWAs	10 mg/m ³
	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³

SAFETY DATA SHEET

Material Name: ProHeart® Tablets

Page 4 of 9

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	3 mg/m ³
Magnesium stearate	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³
Silica colloidal, Ph. Eur.	
Austria OEL - MAKs	4 mg/m ³
Moxidectin	
Zoetis OEL TWA 8-hr	70 µg/m ³
Exposure Controls	
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Wear impervious gloves if skin contact is possible.
Eyes:	Safety glasses or goggles
Skin:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Solid Tablet	Color:	No data available.
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	Methanol Diethylether n-octanol Acetone		
Water Solubility:	Soluble		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)	No data available		
Moxidectin			
Predicted 7 Log D 8.74			
Decomposition Temperature (°C):	No data available.		
Evaporation Rate (Gram/s):	No data available		
Vapor Pressure (kPa):	No data available		
Vapor Density (g/ml):	No data available		
Relative Density:	No data available		
Viscosity:	No data available		
Flammability:			
Autoignition Temperature (Solid) (°C):	No data available		
Flammability (Solids):	No data available		

SAFETY DATA SHEET

Material Name: ProHeart® Tablets

Page 5 of 9

Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients. Toxicological properties of the formulation have not been investigated.

Acute Toxicity: (Species, Route, End Point, Dose)

Moxidectin

Rat Oral LD50 106 mg/kg
Rat Dermal LD50 > 2000mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Irritation / Sensitization: (Study Type, Species, Severity)

Moxidectin

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild
Skin Sensitization - Beuhler Guinea Pig Negative

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Moxidectin

28 Day(s) Mouse Oral 75 mg/kg/day NOEL Central nervous system
28 Day(s) Rat Oral 100 mg/kg/day LOEL Central Nervous System

SAFETY DATA SHEET

Material Name: ProHeart® Tablets

Page 6 of 9

11. TOXICOLOGICAL INFORMATION

13 Week(s) Rat Oral 50 mg/kg/day NOEL Central Nervous System
90 Day(s) Dog Oral 10 mg/kg/day NOEL Central Nervous System

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Moxidectin

Embryo / Fetal Development Rabbit Oral 1 mg/kg bw/day NOEL Maternal toxicity, Not teratogenic
Embryo / Fetal Development Rat Oral 5 mg/kg/day NOEL Negative
Embryo / Fetal Development Rat Oral 5 mg/kg bw/day NOEL Not Teratogenic, Embryotoxicity, Maternal Toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Moxidectin

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vitro HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative
In Vivo Cytogenetics Rat Bone Marrow Negative
In Vivo Unscheduled DNA Synthesis Rat Hepatocyte Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Moxidectin

2 Year(s) Mouse Oral 30 mg/kg/day NOEL Not carcinogenic
2 Year(s) Rat Oral 100 mg/kg/day NOEL Not carcinogenic

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Silica colloidal, Ph. Eur.

IARC:

Group 3 (Not Classifiable)

SAFETY DATA SHEET

Material Name: ProHeart® Tablets

Page 7 of 9

12. ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties of the formulation have not been investigated. See Aquatic toxicity data of the active ingredient, below:

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Moxidectin

<i>Lepomis macrochirus</i> (Bluegill Sunfish)	LC50	96 Hours	0.62 ppb
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	LC50	96 Hours	0.16 ppb
<i>Daphnia Magna</i> (Water Flea)	EC50	48 Hours	30 ppt
<i>Selenastrum capricornutum</i> (Green Alga)	EC50	72 Hours	> 87 ppb

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Moxidectin

Predicted 7 Log D 8.74

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, ADG or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

SAFETY DATA SHEET

Material Name: ProHeart® Tablets

Page 8 of 9

15. REGULATORY INFORMATION

Microcrystalline cellulose

CERCLA/SARA 313 Emission reporting

Australia (AICS):

Not Listed

Present

Magnesium stearate

CERCLA/SARA 313 Emission reporting

Australia (AICS):

Not Listed

Present

Silica colloidal, Ph. Eur.

CERCLA/SARA 313 Emission reporting

Australia (AICS):

Not Listed

Present

Moxidectin

CERCLA/SARA 313 Emission reporting

Standard for the Uniform Scheduling

for Drugs and Poisons:

APVMA Number:

Not Listed

Schedule 5

49629

47340

47339

45925

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H301 - Toxic if swallowed

H316 - Causes mild skin irritation

H319 - Causes serious eye irritation

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

T - Toxic

Xi - Irritant

N - Dangerous for the environment

R25 - Toxic if swallowed.

R36 - Irritating to eyes.

SAFETY DATA SHEET

Material Name: ProHeart® Tablets

Page 9 of 9

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 13 - Disposal Considerations. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

This SDS replaces version issued: October 2015

End of Safety Data Sheet