

Section 1 - Identification of the Material and Supplier

Zoetis Australia Pty Ltd

ABN 94 156 476 425

Level 6, 5 Rider Blvd

Rhodes NSW 2138 AUSTRALIA

Tel: 1800 814 883

Fax: (02) 8876 0444

Email: australia.animalhealth@zoetis.com



| | |
|-------------------------|--|
| Chemical nature: | Moxidectin as inert microspheres |
| Trade Name: | ProHeart® SR-12 Injection Once-A-Year Heartworm Preventative for Dogs |
| Other Names: | Proheart for dogs |
| Product Code: | 51805 |
| Product Use: | Prevention of heartworm and treatment of hookworms in dogs |

Note that this MSDS relates to the Moxidectin microspheres. The other vial in the package contains sterile solution (saline water) which has no known hazards.

| | |
|-----------------------------|---|
| Creation Date: | July, 2012 |
| This version issued: | 1 October 2016 and is valid for 5 years from this date |

Section 2 - Hazards Identification

Appearance: Wax Microspheres with a clear or translucent sterile solution

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 4

Serious Eye Damage/Eye Irritation: Category 2

Specific target organ systemic toxicity (repeated exposure): Category 2

Acute aquatic toxicity: Category 1

Chronic aquatic toxicity: Category 1

Label Elements

| | |
|---------------------------|--|
| Signal Word: | Warning |
| Hazard Statements: | H302 - Harmful if swallowed H319 - Causes serious eye irritation H373 - May cause damage to organs through prolonged or repeated exposure (central nervous system, peripheral nervous system) H410 - Very toxic to aquatic life with long lasting effects |

| | |
|----------------------------------|---|
| Precautionary Statements: | P280 - Wear protective gloves/protective clothing/eye protection/face protection P260 - Do not breathe dust/fume/gas/mist/vapors/spray P270 - Do not eat, drink or smoke when using this product P264 - Wash hands thoroughly after handling P273 - Avoid release to the environment P314 - Get medical attention/advice if you feel unwell P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell P330 - Rinse mouth P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P337 + P313 - If eye irritation persists: Get medical advice/attention P391 - Collect spillage P501 - Dispose of contents/container in accordance with all local and national regulations |
|----------------------------------|---|

SAFETY DATA SHEET



Other Hazards

Short Term:

Can cause eye irritation. Signs and symptoms might include redness, swelling, blurred vision or pain. May cause slight skin irritation. May cause central nervous system effects.

Long Term:

May cause effects on nervous system through prolonged or repeated exposure.

Known Clinical Effects:

Adverse effects associated with therapeutic use include clumsy motion of limbs/trunk (ataxia) drowsiness, depression, salivation.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

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.

Section 3 - Composition/Information on Ingredients

Hazardous

| Hazardous Ingredients | CAS No | Conc,% | GHS Classification |
|------------------------------|---------------|---------------|---|
| Moxidectin | 113507-06-5 | 10 | Acute Tox.3 (H301) Eye Irrit. 2A (H319) Skin Irrit 3 (H316) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410) |
| Sodium chloride | 7647-14-5 | <1 | Not Listed |
| Methylparaben | 99-76-3 | <1 | Not Listed |
| Propylparaben | 94-13-3 | <0.1 | Not Listed |
| Butylated hydroxytoluene | 128-37-0 | ## | Not Listed |
| Sterile Diluent | Not assigned | 80-90 | Not Listed |

Additional Information:

Trace

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non-hazardous ingredients are also possible.

Section 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.

SAFETY DATA SHEET

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: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

Section 5 - Fire Fighting Measures

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

Special Hazards Arising from the Substance or Mixture

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 firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Section 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

Prevent product from entering drains. 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 spill with absorbent material. 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.

Additional Information: Keep out of sewage systems and waterways.

Section 7 - Handling and Storage

Precautions for Safe Handling

SAFETY DATA SHEET

When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): No data available

Section 8 - Exposure Controls and Personal Protection

Control Parameters

Moxidectin
Zoetis OEL TWA 8-hr 70 µg/m³

Butylated hydroxytoluene
Australia TWA 10 mg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section. 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: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure. 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.

Section 9 - Physical and Chemical Properties:

| | | | |
|---------------------------|---------------------------------------|--------------------------|----------------------|
| Physical State: | Wax Microspheres plus sterile diluent | Color: | Clear or translucent |
| Odor: | No data available | Odor Threshold: | No data available |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |

Solvent Solubility: No data available

Water Solubility: No data available

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

SAFETY DATA SHEET

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
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

Section 10 - Stability and Reactivity

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use
Possibility of Hazardous Reactions
Oxidizing Properties: Non-oxidizing
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: Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic vapors.

Section 11 - Toxicological Information

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation. Routes of exposure: eye contact, skin contact

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

Moxidectin

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

Hydroxypropyl methylcellulose

| | | | |
|-----|------|------|----------------|
| Rat | Oral | LD50 | > 10,000 mg/kg |
|-----|------|------|----------------|

Butylated hydroxytoluene

| | | | |
|-------|-----------------|-------|------------|
| Rat | Oral | LD50 | 1700 mg/kg |
| Mouse | Oral | LD50 | 650 mg/kg |
| Rat | Oral | LD50 | 890 mg/kg |
| Mouse | Intraperitoneal | LD 50 | 138 mg/kg |

Sodium chloride

| | | | |
|-------|------|------|------------|
| Rat | Oral | LD50 | 3000 mg/kg |
| Mouse | Oral | LD50 | 4000 mg/kg |

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Ingestion Acute Toxicity Harmful if swallowed.

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

Moxidectin

SAFETY DATA SHEET

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

Butylated hydroxytoluene

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Moderate

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Irritation / Sensitization Comments: May cause eye irritation.
Skin Irritation / Sensitization May cause mild skin irritation.

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
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

Butylated hydroxytoluene

4 Week(s) Rat Oral 5185 mg/kg LOEL Liver
4 Day(s) Mouse Oral 2000 mg/kg LOEL Liver, Kidney, Ureter, Bladder

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

Butylated hydroxytoluene

Embryo / Fetal Development Rat Oral 6 g/kg LOEL Teratogenic,

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.

Butylated hydroxytoluene

IARC: Group 3 (Not Classifiable)

Product Level Toxicity Data

Acute Toxicity Estimate (ATE), Oral 1064 mg/kg

SAFETY DATA SHEET

Section 12 - Ecological Information

Environmental Overview: Environmental properties of the formulation have not been investigated. The following information is available for the individual ingredients. The active ingredient in this formulation is Very toxic to aquatic organisms. May have long-term effects on the aquatic environment. Releases to the environment should be avoided.

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 |

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested

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

Section 13 - Disposal Considerations

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities use a commercial waste disposal service.

Section 14 - Transport Information

ADG: Not regulated for transportation due to Special Provision AU01

As of January 1, 2015, materials offered for transport that are classified for transportation only as Marine Pollutants and which are packaged in single or combination packaging's containing a net quantity per single or inner packaging of 5 Liters or less for liquids or having a net mass per single or inner packaging of 5 kilograms or less for solids are NOT subject to ICAO/IATA, IMDG, or ADR transport regulations provided the general packaging requirements of those regulations are met.

UN number: UN 3082

UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCES, LIQUID, N.O.S.
(moxidectin)

Transport hazard class(es): 9

Packing group: III

Environmental Hazard(s): Marine Pollutant

Please refer to the applicable dangerous goods regulations for additional information. Transport according to the requirements of the appropriate regulatory body.

SAFETY DATA SHEET

Section 15 - Regulatory Information

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

Poison Schedule Schedule 4

Sodium chloride

Australia (AICS): Present

Methylparaben

Australia (AICS): Present

Propylparaben

Australia (AICS): Present

Butylated hydroxytoluene

Australia (AICS): Present

Section 16 - Other Information

This MSDS contains only safety-related information. For other data see product literature.

Acronyms:

| | |
|--------------|---|
| ADG Code | Australian Code for the Transport of Dangerous Goods by Road and Rail (7 th edition) |
| AICS | Australian Inventory of Chemical Substances |
| SWA | Safe Work Australia, formerly ASCC and NOHSC |
| CAS number | Chemical Abstracts Service Registry Number |
| Hazchem Code | Emergency action code of numbers and letters that provide information to emergency services especially firefighters |
| IARC | International Agency for Research on Cancer |
| NOS | Not otherwise specified |
| NTP | National Toxicology Program (USA) |
| R-Phrase | Risk Phrase |
| SUSMP | Standard for the Uniform Scheduling of Medicines & Poisons |
| UN Number | United Nations Number |

This version issued: 1 October 2016 and is valid for 5 years from this date

Supersedes: Revision issued November 2014

Revision History:

| Date of Revision | Reason |
|------------------|-----------------------------------|
| October 2015 | Update to Zoetis name and address |
| 01 Oct 2016 | Update to GHS format. |
| | |
| | |

Contact Points:

| | |
|--------------------------|--------------|
| Zoetis | 1800 814 883 |
| Police and Fire Brigade: | Dial 000 |

SAFETY DATA SHEET

Issued by: Zoetis Australia Pty Ltd

Phone: 1800 814 883

Poisons Information Centre: 13 11 26 from anywhere in Australia, (0800 764 766 in New Zealand)

If ineffective:

**Dial Poisons Information Centre
(13 11 26 from anywhere in Australia)**

THIS SDS SUMMARISES OUR CURRENT AND BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION ABOUT THE PRODUCT DETAILED IN THIS SDS, AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE FOR THE RECOMMENDED USE. EACH USER OF THE PRODUCT MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THEIR OWN WORKPLACE. IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT ZOETIS.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)

© 2016 Zoetis Inc, All rights reserved.

End of Safety Data Sheet

SAFETY DATA SHEET