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

Product Identifier

Material Name: PROHEART® 6

Trade Name: ProHeart®
Synonyms: Moxidectin Sustained Release Injectable for Dogs, Moxidectin 10%
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

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

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):


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

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxidectin</td>
<td>113507-06-5</td>
<td>Not Listed</td>
<td>Acute Tox.3 (H301) Eye Irrit. 2A (H319) Skin Irrit 3 (H316) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)</td>
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<td></td>
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<tr>
<td>Sodium chloride</td>
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<td>231-598-3</td>
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<tr>
<td>Methylparaben</td>
<td>99-76-3</td>
<td>202-785-7</td>
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<td>&lt;1</td>
<td></td>
</tr>
<tr>
<td>Propylparaben</td>
<td>94-13-3</td>
<td>202-307-7</td>
<td>Not Listed</td>
<td>&lt;0.1</td>
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<tr>
<td>Butylated hydroxytoluene</td>
<td>128-37-0</td>
<td>204-881-4</td>
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<td>##</td>
<td></td>
</tr>
</tbody>
</table>

ZT00030
SAFETY DATA SHEET

Material Name: PROHEART® 6
Revision date: 20-Aug-2015

Additional Information:
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.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

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: 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

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 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
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.

7. HANDLING AND STORAGE

Precautions for Safe Handling
- 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

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters
- Refer to available public information for specific member state Occupational Exposure Limits.

Moxidectin
- Zoetis OEL TWA 8-hr: 70 µg/m³

Sodium chloride
- Latvia OEL - TWA: 5 mg/m³
- Lithuania OEL - TWA: 5 mg/m³

Butylated hydroxytoluene
- ACGIH Threshold Limit Value (TWA): 2 mg/m³
- Australia TWA: 10 mg/m³
- Austria OEL - MAKs: 10 mg/m³
- Belgium OEL - TWA: 2 mg/m³
- Bulgaria OEL - TWA: 10.0 mg/m³
- Denmark OEL - TWA: 10 mg/m³
- Finland OEL - TWA: 10 mg/m³
- France OEL - TWA: 10 mg/m³
- Germany - TRGS 900 - TWAs: 10 mg/m³
- Germany (DFG) - MAK: 10 mg/m³
- Greece OEL - TWA: 10 mg/m³
- Ireland OEL - TWAs: 10 mg/m³
- Portugal OEL - TWA: 2 mg/m³
- Slovenia OEL - TWA: 10 mg/m³
- Spain OEL - TWA: 10 mg/m³
- Switzerland OEL - TWAs: 10 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Wax Microspheres plus sterile diluent
Odor: No data available.
Molecular Formula: Mixture
Color: Clear or translucent
Odor Threshold: No data available.
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 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
  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: Non-oxidizing
  Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
10. STABILITY AND REACTIVITY

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.

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
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
11. TOXICOLOGICAL INFORMATION

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 LOAEL Liver
- 4 Day(s) Mouse Oral 2000 mg/kg LOAEL 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
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)

<table>
<thead>
<tr>
<th>Species/Strain</th>
<th>Method</th>
<th>End Point</th>
<th>Duration</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lepomis macrochirus (Bluegill Sunfish)</td>
<td>LC50</td>
<td>96 Hours</td>
<td>0.62 ppb</td>
<td></td>
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<tr>
<td>Oncorhynchus mykiss (Rainbow Trout)</td>
<td>LC50</td>
<td>96 Hours</td>
<td>0.16 ppb</td>
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</tr>
<tr>
<td>Daphnia Magna (Water Flea)</td>
<td>EC50</td>
<td>48 Hours</td>
<td>30 ppt</td>
<td></td>
</tr>
<tr>
<td>Selenastrum capricornutum (Green Alga)</td>
<td>EC50</td>
<td>72 Hours</td>
<td>&gt; 87 ppb</td>
<td></td>
</tr>
</tbody>
</table>

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

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Should not be released into the environment. Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. 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

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 packagings 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. Refer to ICAO/IATA A197, IMDG 2.10.2.7, ADR SP 375.

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.

DOT / ANTT: Not regulated for transportation

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision B
This product has been classified in accordance with the hazard criteria of the CPR and the SDS contains all of the information required by the CPR.

Moxidectin
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Standard for the Uniform Scheduling
for Drugs and Poisons:
Schedule 4
Schedule 5
Schedule 6
Schedule 7
EU EINECS/ELINCS List Not Listed

Sodium chloride
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 231-598-3

Methylparaben
CERCLA/SARA 313 Emission reporting Not Listed
California Proposition 65 Not Listed
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 202-785-7

Propylparaben
15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
<th>Code</th>
</tr>
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<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
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<tr>
<td>California Proposition 65</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<tr>
<td>EU EINECS/ELINCS List</td>
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Sterile Diluent

<table>
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<th>Category</th>
<th>Description</th>
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<tbody>
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</table>

Butylated hydroxytoluene

<table>
<thead>
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<th>Description</th>
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<tr>
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<td>California Proposition 65</td>
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</tr>
<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>Australia (AICS):</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
<td>204-881-4</td>
<td></td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

- Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
- Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life
- Hazardous to the aquatic environment, chronic toxicity-Cat.1; H410 - Very toxic to aquatic life with long lasting effects
- Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
- Skin corrosion/irritation-Cat.3; H316 - Causes mild skin irritation

Data Sources: The data contained in this SDS 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 11 - Toxicology Information. Updated Section 14 - Transport Information. Updated Section 7 - Handling and Storage. Updated Section 15 - Regulatory Information. Updated Section 16 - Other Information.

Prepared by: Toxicology and Hazard Communication Zoetis Global Risk Management

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.

End of Safety Data Sheet