

SAFETY DATA SHEET



Revision date: 21-Aug-2015

Version: 2.0

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

Product Identifier

Material Name: PROHEART® 12

Trade Name: ProHeart®

Synonyms: ProHeart SR-12; 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

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison and Drug Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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

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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):

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Moxidectin	113507-06-5	Not Listed	Acute Tox.3 (H301) Eye Irrit. 2A (H319) Skin Irrit 3 (H316) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	10
Sodium chloride	7647-14-5	231-598-3	Not Listed	<1
Methylparaben	99-76-3	202-785-7	Not Listed	<1
Propylparaben	94-13-3	202-307-7	Not Listed	<0.1
Butylated hydroxytoluene	128-37-0	204-881-4	Not Listed	##

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Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sterile Diluent	Not assigned	Not Listed	Not Listed	80-90

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.

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

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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

Exposure Controls

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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:	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.

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		
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.

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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

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

Moxidectin

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	<i>Salmonella</i> , <i>E. coli</i>	Negative
<i>In Vitro</i> HGPRT Forward Gene Mutation Assay	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vivo</i> Cytogenetics	Rat Bone Marrow	Negative
<i>In Vivo</i> 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

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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

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

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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

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15. REGULATORY INFORMATION

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	202-307-7

Sterile Diluent

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Butylated hydroxytoluene

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	204-881-4

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 14 - Transport Information. Updated Section 7 - Handling and Storage.
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 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