

SAFETY DATA SHEET



Revision date: 05-Jan-2015

Version: 4.2

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

Product Identifier

Material Name: Moxidectin 0.5% Pour-On

Trade Name: CYDECTIN
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 Control 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: Clear, amber liquid

Classification of the Substance or Mixture

GHS - Classification

Acute aquatic toxicity: Category 1
Chronic aquatic toxicity: Category 1

EU Classification:

EU Indication of danger: Dangerous for the Environment

EU Symbol: N

EU Risk Phrases:

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

Label Elements

Signal Word: Warning

Hazard Statements: H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements: P273 - Avoid release to the environment
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards

Short Term:

Known Clinical Effects:

May be harmful if swallowed. May cause slight skin irritation. (based on components)
Adverse effects associated with therapeutic use include : clumsy motion of limbs/trunk (ataxia), drowsiness, depression, salivation.
Non-Hazardous Substance. Non-Dangerous Goods.

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

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Citric Acid	77-92-9	201-069-1	Not Listed	Not Listed	1
Moxidectin	113507-06-5	Not Listed	T;R25 Xi;R36 N;R50/53	Acute Tox.3 (H301) Eye Irrit. 2A (H319) Skin Irrit 3 (H316) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	0.5
Butylated hydroxyanisole	25013-16-5	246-563-8	Xn R40	Carc 2 (H351)	<0.1

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Propylene glycol	57-55-6	200-338-0	Not Listed	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and 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.

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- 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

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.

7. HANDLING AND STORAGE

Precautions for Safe Handling

When handling, use appropriate personal protective equipment (see Section 8). Use with adequate ventilation. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

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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

Butylated hydroxyanisole

Germany - TRGS 900 - TWAs 20 mg/m³

Germany (DFG) - MAK 20 mg/m³

Propylene glycol

Australia TWA 150 ppm
474 mg/m³
10 mg/m³

Ireland OEL - TWAs 150 ppm
470 mg/m³
10 mg/m³

Latvia OEL - TWA 7 mg/m³

Lithuania OEL - TWA 7 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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Clear amber
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.

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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.
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: 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: skin contact , eye contact , inhalation

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

Moxidectin

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

Propylene glycol

Rat Oral LD 50 22,000 mg/kg
Mouse Oral LD 50 24,900mg/kg
Rabbit Dermal LD 50 20,800mg/kg

Butylated hydroxyanisole

Rat Oral LD50 2000 mg/kg
Mouse Oral LD 50 1100mg/kg
Rat Intraperitoneal LD 50 881mg/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.

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

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11. TOXICOLOGICAL INFORMATION

Moxidectin

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

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Citric Acid

Eye Irritation Rabbit Irritant
Skin 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
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 hydroxyanisole

12 Day(s) Rat Oral 3300 mg/kg LOAEL Liver, Blood

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 hydroxyanisole

Embryo / Fetal Development Rat Oral 30 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

Butylated hydroxyanisole

In Vivo Micronucleus Bone Marrow Negative
In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative

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

Moxidectin

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

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11. TOXICOLOGICAL INFORMATION

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

Butylated hydroxyanisole

Two Year(s) Rat Oral 728 g/kg/day Gastrointestinal system, Tumors

Two Year(s) Rat Oral 874 g/kg/day Gastrointestinal system, Endocrine system, Tumors

Carcinogen Status: See below

Butylated hydroxyanisole

IARC: Group 2B (Possibly Carcinogenic to Humans)
NTP: Reasonably Anticipated To Be A Human Carcinogen

12. ECOLOGICAL INFORMATION

Environmental Overview: Very toxic to aquatic life with long lasting effects. Releases to the environment should be avoided.

Toxicity:

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

Moxidectin

Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours 0.62 ppb

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 0.16 ppb

Daphnia Magna (Water Flea) EC50 48 Hours 30 ppt

Selenastrum capricornutum (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:

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. 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.

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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:

Non-controlled

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Citric Acid

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	201-069-1

Moxidectin

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed

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15. REGULATORY INFORMATION

Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4 Schedule 5 Schedule 6 Schedule 7
EU EINECS/ELINCS List	Not Listed
Butylated hydroxyanisole	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen initial date 1/1/90
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	246-563-8
Propylene glycol	
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	200-338-0

16. OTHER INFORMATION

Text of R phrases and 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

N - Dangerous for the environment
T - Toxic
Xi - Irritant

R25 - Toxic if swallowed.
R36 - Irritating to eyes.
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 14 - Transport Information. Updated Section 3 - Composition / Information on Ingredients.

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

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