SAFETY DATA SHEET

Zoetis New Zealand Limited



Section 1: Identification of the Substance and Supplier

Trade Name: CYDECTIN® Plus fluke Pour-On

ACVM Registration No.: A010651

Classification: Unrestricted

Recommended Use: Topical ectoparasiticide / endoparasiticide for treatment and control of

liver fluke, internal and external parasites of cattle.

Company Details: Zoetis New Zealand Limited

Address: Level 4, 8 Mahuhu Crescent

> **Auckland Central** Auckland 1010 New Zealand

Telephone No.: 0800 963 847 (Business Hours)

Emergency Telephone

No.:

National Poisons Centre: 0800 POISON (0800 764 766) **Emergency Services:** In an emergency dial 111

Date of Preparation: 01 July 2019

Section 2: Hazards Identification

Hazard Classification: 6.1D,6.5B, 6.8B, 6.8C, 6.9B, 9.1A, 9.2C, 9.3C, 9.4B

WARNING - KEEP OUT OF REACH OF CHILDREN Priority Identifier(s):

ECOTOXIC

Secondary Identifier(s): May be harmful if swallowed, inhaled or absorbed through the skin. 6.1D

> 6.5B May cause an allergic skin reaction. Avoid skin contact.

6.8B Suspected of damaging fertility or the unborn child from repeated

oral exposure.

May cause harm to breast-fed children from repeated oral 6.8C

6.9B exposure.

May cause target organ damage from repeated oral exposure at

9.1A high doses.

Very toxic to aquatic organisms with long-lasting effects. Avoid

9.2C contamination of any water supply with product or empty container.

9.3C Harmful to the soil environment.

9.4B Harmful to terrestrial vertebrates.

Toxic to terrestrial invertebrates.

Section 3: Composition / Information on Ingredients			
Chemical Identity of Ingredients			
Ingredient	CAS No.	Concentration	
Moxidectin	113507-06-5	0.5% w/v	
Triclabendazole	68786-66-3	20% w/v	
Butylated hydroxytoluene	128-37-0	Proprietary	
Other ingredients determined not to be hazardous.	-	To 100% w/v	

This is a commercial product whose exact ratio of components may vary. Trace quantities of impurities are also likely.

Section 4: First Aid Measures

Necessary First Aid Measures:

For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately. If the patient is not breathing begin artificial respiration and seek medical advice immediately. Never give fluids or induce vomiting if a patient is unconscious or convulsing, regardless of injury.

Ingestion: DO NOT induce vomiting. If the patient is conscious wash

mouth out with water. Do not give anything by mouth to an unconscious person. Seek medical advice immediately.

Eye Contact: Flush the eye(s) out with running water for at least 15

minutes. Removal of contact lenses should be done with caution within 5 minutes of exposure. If symptoms develop

seek medical advice immediately.

Skin Contact: Remove any contaminated clothing and wash the affected

area immediately with soap and water. If symptoms develop

seek medical advice immediately.

Inhalation: Move the patient to fresh air. If symptoms develop seek

medical advice immediately.

Poisoning Symptoms: No specific information available.

Workplace Facilities: No specific facilities required. Standard emergency equipment must be

available.

Hygiene Practices: Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or

vapours. Do not eat, drink or smoke while using this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any

protective clothing after use.

Notes for Medical

Personnel:

Treatment of exposure should be directed at the control of symptoms and the

clinical condition of the patient. Note the nature of this product.

Section 5: Fire-Fighting Measures

Type of hazard: This product is non-flammable and non-explosive.

Fire Hazard Properties: This product does not burn. There is no risk of an explosion from this

product under normal circumstances if it is involved in a fire. It will produce only minor quantities of decomposition products at temperatures normally achieved in a fire. Likely to decompose only after heating to dryness followed by further strong heating. Do not allow fire water to enter

waterways.

Regulatory Requirements: Not applicable.

Extinguishing Media &

Methods:

Use dry chemical, carbon dioxide or water to extinguish fires involving this

product.

Hazchem Code: 3Z

Recommended Protective

Clothing:

During large-scale fire fighting operations wear approved positive pressure,

self-contained breathing apparatus and full protective turn-out gear.

Section 6: Accidental Release Measures

Personal Precautions: Personnel involved in clean-up should wear appropriate personal

protective equipment to minimise exposure. This may include eye

protection, chemically resistant gloves, boots and overalls.

Environmental Precautions:

Prevent material from entering surface water drains or waterways. If a significant quantity of material enters drains, advise emergency services.

Procedure for Spills:

- 1. Non-essential personnel should be evacuated from the affected area.
- 2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage.
- 3. Absorb the spill with an absorbent material (e.g. sand).
- 4. Collect the spilled material into labelled containers for disposal, minimising dust generation.
- 5. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains.

Procedure for Disposal:

Contaminated material must be disposed of at an approved landfill or other approved facility in accordance with local, regional and national requirements. Avoid contamination of any water supply with product or empty container.

Section 7: Handling and Storage

Handling

Precautions for Safe

Handling:

Keep exposure to this product to a minimum and minimise the quantities kept in work areas. Ensure the personal protective measures outlined in Section 8 are followed, and avoid contact or contamination with incompatible materials listed in Section 10. The measures detailed under "Storage" below should be followed during handling to minimise risks to persons using the product in the workplace.

Regulatory Requirements:

Not required.

Handling Practices:

Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.

Approved Handlers:

Approved handlers are not required for this product.

Conditions for Safe

Storage:

Store below 25°C (Air Conditioning). Protect from light. Keep out of reach of children. Store in a well ventilated area in the original container, tightly closed, away from foodstuffs.

Store Site Requirements:

A requirement for an emergency management plan, secondary containment and signage is applicable when quantities of 100 L or more are stored.

Packaging:

Packaging Schedule 3 (UN Packing Group III) for quantities > 5 L (Hazardous Substances Packaging Regulations 2001). Store in the

original container, away from foodstuffs.

Section 8: Exposure Control / Personal Protection

Always Read and Follow the Label Instructions and Warnings

Workplace Exposure Guidelines

Workplace Exposure Standards:

A time weighted average (TWA) concentration for an 8-hour day and a 5-day week has not been established by NOHSC Australia for any of the major ingredients in this product. There is a blanket limit of 10 mg/m³ for dusts or mists when limits have not otherwise been established.

Application in the Workplace:

The nature of this product makes it unlikely that this level will be approached during normal handling.

Exposure Standards Outside the Workplace:

Moxidectin:

ADE: 0.002 mg/kg bw/dayPDE_{food}: 0.0014 mg/kg bw/day

PDE_{drinking water}: 0.0004 mg/kg bw per day
 PDE_{dermal}: 0.0002 mg/kg bw per day
 TEL_{skin surface deposition}: 0.03 mg/m2

EEL_{water}: 0.0000003 mg/L

Triclabendazole:

ADE: 0.003 mg/kg bw/dayPDE_{food}: 0.0021 mg/kg bw/day

PDE_{drinking water}: 0.0006 mg/kg bw per day PDE_{dermal}: 0.0003 mg/kg bw per day TEL_{skin surface deposition}: 0.05 mg/m2

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protection:

The following instructions are for those coming into frequent and / or lengthy contact with this product. For occasional handling employ precautions suitable for the conditions under which the product is being handled.

Hands: Impervious protective gloves should be worn when handling this product to prevent irritation. Consult AS/NZS 2161 for

quidance.

Eyes: Protective eyewear should be worn when handling this

product as eye contact may prove painful and dangerous, and should be avoided. Consult AS/NZS 1336 and 1337 for

guidance.

Skin: Clean overalls or protective clothing, including safety boots,

should be worn. Consult AS/NZS 2919 and 2210 for guidance.

Respiratory: Respiratory protection is not normally required; however, if the

product is being handled in dusty or confined conditions, use of a mask or respirator may be preferred. Consult AS/NZS

1715 for guidance.

General Hygiene: Change work clothes regularly. Avoid ingestion, contact with skin and eyes,

and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking

or smoking and after work. Wash any protective clothing after use.

Section 9: Physical and Chemical Properties

Appearance: Clear amber liquid

Odour: Mild odour

Specific Gravity / Density: No data available

Freezing / Melting Point: No data available. Liquid at normal temperature

Boiling Point: No data available.

pH: No data available

Solubility in Water: Insoluble

Flashpoint: Not applicable. This product is not flammable

Oxidising Properties: Not applicable. This product is not an oxidiser

Corrosive Properties: Not applicable. This product is not corrosive

Vapour Pressure: No data available

Section 10: Stability and Reactivity

Stability of the Substance: This product is unlikely to react or decompose under normal storage

conditions.

Conditions to Avoid: Store as recommended. No specific conditions to avoid.

Material to Avoid: No specific materials to avoid. As a precautionary measure, keep away

from strong oxidisers.

Hazardous Decomposition

Products:

This product is unlikely to spontaneously decompose.

Hazardous Polymerisation: This product is unlikely to spontaneously polymerise.

Specific Data: No specific data available.

Section 11: Toxicological Information		
HSNO Classifications		
6.1D	May be harmful if swallowed, inhaled or absorbed through the skin.	
6.5B	May cause an allergic skin reaction. Avoid skin contact.	
6.8B	Suspected of damaging fertility or the unborn child from repeated oral exposure.	
6.8C	May cause harm to breast-fed children from repeated oral exposure.	
6.9B	May cause target organ damage from repeated oral exposure at high doses.	

Acute Effects

Acute Toxicity:

(Species, Route, End Point, Dose)

Moxidectin:

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

Triclabendazole:

- Rat Oral LD50 > 8000 mg/kg
- Rat Inhalation LC50/4h > 500 mg/m³
- Rat Dermal LD50 > 4000 mg/kg

Butylated hydroxytoluene:

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

Irritation / Sensitisation:

(Study Type, Species, Severity)

Moxidectin:

- Eye irritation Rabbit Moderate
- Skin irritation Rabbit Mild
- Skin sensitisation Beuhler Guinea Pig Negative

Triclabendazole:

- Eye irritation Rabbit Non-irritating
- Skin irritation Rabbit Slight

Butylated hydroxytoluene:

- Eye irritation Rabbit Moderate
- Skin irritation Rabbit Moderate

Chronic / Long Term Effects

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

Triclabendazole:

- Reproductive & Fertility Rat Oral 5.5 mg/kg/day NOEL No effects at max dose
- Fertility & Embryonic Development Rat Oral 50 mg/kg/day Maternal toxicity, Not teratogenic
- Embryo / Foetal Development Rabbit Oral 3 mg/kg/day fetotoxicity

Butylated hydroxytoluene:

• Embryo / Foetal Development Rat Oral 6 g/kg LOEL Teratogenic

Moxidectin: Laboratory rodent reproductive studies reported foetal malformations, decreased

number of live births, reduced pup weights and neonatal & lactational deaths [lowest NOEL 0.4 mg/kg/day]. A chronic feeding study (90 days; 0 to 1.6 mg/kg/d) induced toxicity in dogs. At the highest dose lacrimation, tremors, salivation, slight ataxia and a languid appearance were reported. Dose dependant reductions in absolute body weight and food consumption were noted [NOEL 0.3 mg/kg]. In a second study (52 weeks; 0-1.15 mg/kg/d), no signs of toxicity occurred and body weights remained comparable to controls throughout the study [NOEL 1.15 mg/kg].

Moxidectin is not mutagenic or carcinogenic.

Triclabendazole: A 13 week study of dogs fed a diet containing 0.35-39 mg/kg triclabendazole

showed depressed weight gains and hepatotoxicity at high doses, LOAEL 3.5

mg/kg/day.

Butylated hydroxytoluene:

Repeated oral doses caused weight loss in laboratory animal studies (NOAEL 75

ne: mg/kg).

Section 12: Ecotoxicity Information

HSNO Classifications

- **9.1A** Very toxic to aquatic organisms with long-lasting effects. Avoid contamination of any water supply with product or empty container.
- **9.2C** Harmful to the soil environment.
- **9.3C** Harmful to terrestrial vertebrates.
- **9.4B** Toxic to terrestrial invertebrates.

The environmental characteristics of this material have not been fully evaluated. Avoid contamination of any water supply with product or empty container.

Ecotoxicity Effects

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 capricomutum (Green Alga) EC50 72 Hours > 87 ppb

Triclabendazole:

• Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 0.14 mg/L

Environmental Fate

No information available.

Section 13: Disposal Considerations

Product Disposal: Preferably dispose of product by use in accordance with label directions.

Otherwise dispose of product at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of

any water supply with product.

Container Disposal: Dispose of empty containers by wrapping in paper and putting in garbage for

disposal at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply

with empty container.

Section 14: Transport Information

Dangerous Goods Classification

UN No.: 3082
Class: 9
Packing Group: III

Proper Shipping Name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.

(Moxidectin 0.5 %)

Section 15: Regulatory Information

HSNO Approval No.: HSR100493

HSNO Controls: See <u>www.epa.govt.nz</u> for controls

ACVM Registration No.: A010651

ACVM Controls: See www.foodsafety.govt.nz for registration conditions

Section 16: Other Information

Note: This product is a veterinary medicine and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to the Government health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

CONTACT POINT: Zoetis New Zealand Limited: 0800 963 847 (Business Hours)

National Poisons Centre: 0800 POISON (0800 764 766)

Emergency Services: Dial 111

This Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products.

PLEASE READ ALL LABELS CAREFULLY BEFORE USING PRODUCT.

If clarification of further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

® Registered trademark © 2019 All rights reserved