according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

#### **SECTION 1. IDENTIFICATION**

Product name : Pyrantel Pamoate / Moxidectin Formulation

Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the Hazardous Products Regulations

Reproductive toxicity : Category 2

Specific target organ toxicity

- repeated exposure

: Category 1 (Central nervous system)

**GHS** label elements

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H361d Suspected of damaging the unborn child.

H372 Causes damage to organs (Central nervous system)

through prolonged or repeated exposure.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe dust, fume, gas, mist, vapors or spray.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves, protective clothing, eye protection

and face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical attention.

according to the Hazardous Products Regulations



# **Pyrantel Pamoate / Moxidectin Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

Other hazards

None known.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1)		22204-24-6	38.3
Propylene glycol	1,2-Propanediol	57-55-6	15
Glycerine	1,2,3- Propanetriol	56-81-5	10
Moxidectin	No data availa- ble	113507-06-5	1
Ethanol#	Ethyl alcohol	64-17-5	0.1

<sup>#</sup> Voluntarily-disclosed substance

### **SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention.
Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms : Suspected of damaging the unborn child.

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04/02/2024 06/26/2024 4892850-00013 Date of first issue: 09/17/2019 3.9

and effects, both acute and

delayed

Causes damage to organs through prolonged or repeated

exposure.

Protection of first-aiders First Aid responders should pay attention to self-protection,

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

Exposure to combustion products may be a hazard to health.

fighting

Hazardous combustion prod-

Carbon oxides Nitrogen oxides (NOx)

Sulfur oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

> Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

according to the Hazardous Products Regulations



# **Pyrantel Pamoate / Moxidectin Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust, fume, gas, mist, vapors or spray.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1)	22204-24-6	TWA	250 μg/m3 (OEB 2)	Internal
Propylene glycol	57-55-6	TWA (Va- pour and aerosols)	50 ppm 155 mg/m³	CA ON OEL
		TWA (aero- sol)	10 mg/m³	CA ON OEL
Glycerine	56-81-5	TWA (Mist)	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Mist)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable mist)	3 mg/m³	CA BC OEL
		TWAEV (Mist)	10 mg/m <sup>3</sup>	CA QC OEL
Moxidectin	113507-06-5	TWA	10 μg/m3 (OEB 3)	Internal

according to the Hazardous Products Regulations



# **Pyrantel Pamoate / Moxidectin Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Ethanol	64-17-5	TWA	1,000 ppm	CA AB OEL
			1,880 mg/m <sup>3</sup>	
		STEL	1,000 ppm	CA BC OEL
		STEV	1,000 ppm	CA QC OEL
		STEL	1,000 ppm	ACGIH

**Engineering measures** : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face

containment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection. Combined particulates and organic vapor type

Filter type

Hand protection

Material

: Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets,

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : paste

according to the Hazardous Products Regulations



# **Pyrantel Pamoate / Moxidectin Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Color : yellow

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Particle characteristics

Particle size : Not applicable

### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

### Information on likely routes of exposure

Skin contact Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.

#### **Product:**

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Can react with strong oxidizing agents.

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

#### Components:

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Acute oral toxicity : LD50 (Rat): > 24,000 mg/kg

LD50 (Mouse): > 24,000 mg/kg

LD50 (Dog): 2,000 mg/kg

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l

Exposure time: 4 h

according to the Hazardous Products Regulations



# **Pyrantel Pamoate / Moxidectin Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

Glycerine:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

Moxidectin:

Acute oral toxicity : LD50 (Rat): 106 mg/kg

LD50 (Mouse): 42 - 84 mg/kg

Acute inhalation toxicity : LC50 (Rat): 3.28 mg/l

Exposure time: 5 h

Test atmosphere: dust/mist

LC50 (Rat): 2.87 - 4.06 mg/l Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Remarks: No significant adverse effects were reported

Acute toxicity (other routes of :

administration)

LD50 (Rat): 394 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 84 mg/kg

Application Route: Intraperitoneal

LD50 (Rat): > 640 mg/kg

Application Route: Subcutaneous

LD50 (Mouse): 263 mg/kg

Application Route: Subcutaneous

**Ethanol:** 

Acute oral toxicity : LD50 (Rat): 10,470 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male): 116.9 mg/l

Exposure time: 4 h
Test atmosphere: vapor

Acute dermal toxicity : LD50 (Rabbit): > 15,800 mg/kg

Skin corrosion/irritation

Not classified based on available information.

according to the Hazardous Products Regulations



# **Pyrantel Pamoate / Moxidectin Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

**Components:** 

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Glycerine:

Species : Rabbit

Result : No skin irritation

Moxidectin:

Species : Rabbit

Result : Mild skin irritation

**Ethanol:** 

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Propylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Glycerine:

Species : Rabbit

Result : No eye irritation

Moxidectin:

Species : Rabbit

Result : Moderate eye irritation

**Ethanol:** 

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

#### Respiratory sensitization

Not classified based on available information.

#### Components:

Propylene glycol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Moxidectin:

Test Type : Buehler Test Routes of exposure : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

**Ethanol:** 

Test Type : Mouse ear swelling test (MEST)

Routes of exposure : Skin contact
Species : Mouse
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Propylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Glycerine:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: 3.9 06/26/2024

SDS Number: 4892850-00013

Date of last issue: 04/02/2024 Date of first issue: 09/17/2019

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

Moxidectin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster ovary cells

Result: negative

Test Type: in vitro test Test system: Escherichia coli

Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration

Species: Rat

Cell type: Bone marrow

Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with

mammalian liver cells in vivo

Species: Rat

Cell type: Liver cells Result: negative

**Ethanol:** 

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

Application Route: Ingestion

Result: negative

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

#### Carcinogenicity

Not classified based on available information.

### **Components:**

#### Propylene glycol:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

### Glycerine:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

#### Moxidectin:

Species : Mouse
Application Route : Oral
Exposure time : 2 Years

NOAEL : 4.5 mg/kg body weight

Result : negative

Species : Rat
Application Route : Oral
Exposure time : 2 Years

NOAEL : 4.5 mg/kg body weight

Result : negative

Species : Dog Application Route : Oral Exposure time : 1 Years

NOAEL : 0.5 mg/kg body weight

Result : negative

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

# 4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 3,000 mg/kg body weight

Result: No effects on fertility and early embryonic

development were detected.

Test Type: Embryo-fetal development

Species: Rabbit

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Application Route: Oral

Developmental Toxicity: NOAEL: 1,000 mg/kg body weight

Result: No effects on fertility and early embryonic

development were detected.

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Mouse

**Application Route: Ingestion** 

Result: negative

**Glycerine:** 

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

**Application Route: Ingestion** 

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

Moxidectin:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Oral

General Toxicity F1: LOAEL: 0.8 mg/kg body weight Symptoms: Reduced fetal weight., Fetal mortality. Result: No effects on fertility., Some evidence of adverse effects on development, based on animal experiments.

Test Type: Three-generation reproduction toxicity study

Species: Rat

Application Route: Oral

General Toxicity F1: LOAEL: 0.8 mg/kg body weight Symptoms: Reduced fetal weight., Fetal mortality. Result: No effects on fertility., Some evidence of adverse effects on development, based on animal experiments.

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

General Toxicity Maternal: LOAEL: 10 mg/kg body weight Embryo-fetal toxicity.: LOAEL: 10 mg/kg body weight

Result: Skeletal malformations.

Remarks: The effects were seen only at maternally toxic dos-

es.

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

General Toxicity Maternal: LOAEL: 5 mg/kg body weight Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: No teratogenic effects., No embryotoxic effects.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

**Ethanol:** 

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

Application Route: Ingestion

Result: negative

#### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

### Components:

### Moxidectin:

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

#### Repeated dose toxicity

#### Components:

# 4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Species: DogNOAEL: 10 mg/kgLOAEL: 30 mg/kgApplication Route: IngestionExposure time: 3 d

Remarks : No significant adverse effects were reported

Species : Dog NOAEL : 600 mg/kg Application Route : Oral Exposure time : 19 d

Remarks : No significant adverse effects were reported

Species : Dog NOAEL : 600 mg/kg Application Route : Oral Exposure time : 30 d

according to the Hazardous Products Regulations



# **Pyrantel Pamoate / Moxidectin Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 600 mg/kg
Application Route : Oral
Exposure time : 90 d

Remarks : No significant adverse effects were reported

Propylene glycol:

Species : Rat, male

NOAEL : >= 1,700 mg/kg

Application Route : Ingestion

Exposure time : 2 y

Glycerine:

 Species
 : Rat

 NOAEL
 : 0.167 mg/l

 LOAEL
 : 0.622 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

Species : Rat

NOAEL : 8,000 - 10,000 mg/kg

Application Route : Ingestion Exposure time : 2 y

Species : Rabbit

NOAEL : 5,040 mg/kg

Application Route : Skin contact

Exposure time : 45 Weeks

Moxidectin:

Species : Mouse
NOAEL : 3.9 mg/kg
LOAEL : 15.4 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Symptoms : Tremors

Species : Rat

NOAEL : 3.9 mg/kg

LOAEL : 7.9 mg/kg

Application Route : Oral

Exposure time : 13 Weeks

Target Organs : Central nervous system Symptoms : Tremors, Salivation

Species : Dog
NOAEL : 0.3 mg/kg
LOAEL : 0.9 mg/kg
Application Route : Oral
Exposure time : 90 Days

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Target Organs : Central nervous system

Symptoms : Tremors, Lachrymation, Salivation

Species : Dog NOAEL : 1.15 mg/kg Application Route : Oral Exposure time : 52 Weeks

Target Organs : Central nervous system Symptoms : Tremors, Lachrymation

**Ethanol:** 

Species : Rat

NOAEL : 1,730 mg/kg LOAEL : 3,200 mg/kg Application Route : Ingestion Exposure time : 90 Days

#### **Aspiration toxicity**

Not classified based on available information.

#### **Experience with human exposure**

### **Components:**

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea,

Headache, Dizziness, Fever

Moxidectin:

Inhalation : Remarks: No human information is available. Skin contact : Remarks: No human information is available. Eye contact : Remarks: No human information is available. Ingestion : Remarks: No human information is available.

### **SECTION 12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

#### **Components:**

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

Exposure time: 96 h

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l

Exposure time: 7 d

Toxicity to microorganisms : NC

NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 h

Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,955 mg/l

Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10,000 mg/l

Exposure time: 16 h

Method: DIN 38 412 Part 8

Moxidectin:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0006 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 0.0002 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.00003 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 0.087

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

**Ethanol:** 

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l

Exposure time: 72 h

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04/02/2024 06/26/2024 4892850-00013 Date of first issue: 09/17/2019 3.9

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l

Exposure time: 72 h

Toxicity to fish (Chronic tox-

icity)

NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l

Exposure time: 100 d

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 9.6 mg/l

Exposure time: 9 d

Toxicity to microorganisms

EC50 (Protozoa): 5,800 mg/l

Exposure time: 4 h

Persistence and degradability

**Components:** 

Propylene glycol:

Biodegradability Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

**Glycerine:** 

Biodegradability Result: Readily biodegradable.

> Biodegradation: 92 % Exposure time: 30 d

Method: OECD Test Guideline 301D

**Ethanol:** 

Result: Readily biodegradable. Biodegradability

Biodegradation: 84 % Exposure time: 20 d

**Bioaccumulative potential** 

**Components:** 

Propylene glycol:

Partition coefficient: n-

log Pow: -1.07

octanol/water Method: Regulation (EC) No. 440/2008, Annex, A.8

**Glycerine:** 

Partition coefficient: n-

octanol/water

log Pow: -1.75

Moxidectin:

Partition coefficient: n-

octanol/water

log Pow: 4.7

**Ethanol:** 

according to the Hazardous Products Regulations



# **Pyrantel Pamoate / Moxidectin Formulation**

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

Partition coefficient: n-

octanol/water

: log Pow: -0.35

Mobility in soil

No data available

Other adverse effects

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **SECTION 14. TRANSPORT INFORMATION**

### International Regulations

**UNRTDG** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Moxidectin)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

**IATA-DGR** 

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Moxidectin)

956

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen- : 956

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Moxidectin)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **Domestic regulation**

**TDG** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Moxidectin)

Class : 9
Packing group : III
Labels : 9
ERG Code : 171

Marine pollutant : yes(Moxidectin)

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### **SECTION 15. REGULATORY INFORMATION**

The ingredients of this product are reported in the following inventories:

DSL : not determined

AICS : not determined

IECSC : not determined

### **SECTION 16. OTHER INFORMATION**

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA ON OEL : Ontario Table of Occupational Exposure Limits made under

the Occupational Health and Safety Act.

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / STEL : Short-term exposure limit

CA AB OEL / TWA : 8-hour Occupational exposure limit
CA BC OEL / TWA : 8-hour time weighted average
CA BC OEL / STEL : short-term exposure limit

CA ON OEL / TWA : Time-Weighted Average Limit (TWA)
CA QC OEL / TWAEV : Time-weighted average exposure value

CA QC OEL / STEV : Short-term exposure value

according to the Hazardous Products Regulations



# Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/02/2024 3.9 06/26/2024 4892850-00013 Date of first issue: 09/17/2019

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to

compile the Material Safety

**Data Sheet** 

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Revision Date : 06/26/2024 Date format : mm/dd/yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8