

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
8.0	06/18/2025	4892889-00019	Date of first issue: 09/17/2019

### SECTION 1. IDENTIFICATION

Product name : Pyrantel Pamoate / Ivermectin Formulation

#### 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 OSHA Hazard Communication Standard (29 CFR 1910.1200)


Specific target organ toxicity : Category 1 (Central nervous system)  
- single exposure (Oral)

Specific target organ toxicity : Category 1 (Central nervous system)  
- repeated exposure (Oral)

#### Other hazards

None known.

#### GHS label elements

Hazard pictograms	: 
Signal Word	: Danger
Hazard Statements	: H370 Causes damage to organs (Central nervous system) if swallowed. H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.
Precautionary Statements	: <b>Prevention:</b> P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. <b>Response:</b> P314 Get medical attention if you feel unwell. <b>Storage:</b> P405 Store locked up.

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### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
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*	>= 30 - <= 60	TSC
Propylene glycol	57-55-6*	>= 10 - <= 30	TSC
Glycerine	56-81-5*	>= 7 - <= 13	TSC
Ivermectin	70288-86-7*	>= 0.5 - <= 1.5	TSC
Ethanol#	64-17-5*	>= 0.1 - <= 1	TSC

# Voluntarily-disclosed substance

\* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

## 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 if symptoms occur.
- In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.
- 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 unless directed to do so by medical personnel.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Causes damage to organs if swallowed.  
Causes damage to organs through prolonged or repeated exposure if swallowed.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

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Notes to physician : when the potential for exposure exists (see section 8).  
: Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Sulfur oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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, protective equipment and emergency 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

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determine which regulations are applicable.  
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 : Avoid breathing vapors.  
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 locked up.  
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/m <sup>3</sup> (OEB 2)	Internal
Propylene glycol	57-55-6	TWA	10 mg/m <sup>3</sup>	US WEEL
Ivermectin	70288-86-7	TWA	30 µg/m <sup>3</sup> (OEB 3)	Internal
Further information: Skin				
		Wipe limit	300 µg/100 cm <sup>2</sup>	Internal
Ethanol	64-17-5	STEL	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m <sup>3</sup>	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m <sup>3</sup>	OSHA Z-1

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**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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### 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

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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)	:	No data available
Flammability (liquids)	:	Not applicable
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

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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 reactions : Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

### 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: 3,333 mg/kg  
Method: Calculation method  
  
Acute dermal toxicity : Acute toxicity estimate: > 5,000 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  
Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

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### Glycerine:

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

### Ivermectin:

Acute oral toxicity	: LD50 (Rat): 50 mg/kg LD50 (Mouse): 25 mg/kg LD50 (Monkey): > 24 mg/kg Target Organs: Central nervous system Symptoms: Vomiting, Dilatation of the pupil Remarks: No mortality observed at this dose.
Acute inhalation toxicity	: LC50 (Rat): 5.11 mg/l Exposure time: 1 h Test atmosphere: dust/mist
Acute dermal toxicity	: LD50 (Rabbit): 406 mg/kg LD50 (Rat): > 660 mg/kg

### 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.

### Components:

#### Propylene glycol:

Species	: Rabbit
Method	: OECD Test Guideline 404
Result	: No skin irritation

#### Glycerine:

Species	: Rabbit
Result	: No skin irritation

#### Ivermectin:

Species	: Rabbit
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||Result : No 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

#### Ivermectin:

||Species : Rabbit  
||Result : Mild 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.

#### 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

#### Ivermectin:

||Routes of exposure : Dermal  
||Species : Humans  
||Result : Does not cause skin sensitization.

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### 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
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### Propylene glycol:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
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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
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### Glycerine:

Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Result: negative
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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 synthesis in mammalian cells (in vitro)  
Result: negative

### Ivermectin:

Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
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Test Type: DNA damage and repair, unscheduled DNA syn-

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thesis in mammalian cells (in vitro)  
Test system: human diploid fibroblasts  
Result: negative

Test Type: Mouse Lymphoma  
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

### 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

#### Ivermectin:

Species	: Rat
Application Route	: Oral
NOAEL	: 1.5 mg/kg body weight
Result	: negative
Remarks	: Based on data from similar materials

Species	: Mouse
Application Route	: Oral

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NOAEL	: 2.0 mg/kg body weight
Result	: negative
Remarks	: Based on data from similar materials

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

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):

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 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

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Species: Rat  
Application Route: Ingestion  
Result: negative

### Ivermectin:

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 0.6 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

Effects on fetal development : Test Type: Development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: NOAEL: 0.2 mg/kg body weight  
Result: Teratogenic effects., Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 0.4 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected.  
Remarks: The mechanism or mode of action may not be relevant in humans.

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Result: Teratogenic effects., Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

### Ethanol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### STOT-single exposure

Causes damage to organs (Central nervous system) if swallowed.

### Components:

#### Ivermectin:

Target Organs : Central nervous system  
Assessment : Causes damage to organs.

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### STOT-repeated exposure

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

#### Components:

##### Ivermectin:

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	: Dog
NOAEL	: 10 mg/kg
LOAEL	: 30 mg/kg
Application Route	: Ingestion
Exposure 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
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

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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

### Ivermectin:

Species	: Dog
NOAEL	: 0.5 mg/kg
LOAEL	: 1 mg/kg
Application Route	: Oral
Exposure time	: 14 Weeks
Target Organs	: Central nervous system
Symptoms	: Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species	: Monkey
NOAEL	: 1.2 mg/kg
Application Route	: Oral
Exposure time	: 2 Weeks
Remarks	: No significant adverse effects were reported

Species	: Rat
NOAEL	: 0.4 mg/kg
LOAEL	: 0.8 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: spleen, Bone marrow, Kidney

### 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):**

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Ingestion	: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea, Headache, Dizziness, Fever
<b>Ivermectin:</b>	
Skin contact	: Remarks: Can be absorbed through skin.
Eye contact	: Remarks: May irritate eyes.
Ingestion	: Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vomiting, anorexia, Lack of coordination

## 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
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 (Chronic toxicity)	: NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l Exposure time: 7 d
Toxicity to microorganisms	: 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

#### **Ivermectin:**



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Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l Exposure time: 96 h  LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0.000025 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1 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  EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l Exposure time: 72 h
Toxicity to fish (Chronic toxicity)	: NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l Exposure time: 100 d
Toxicity to daphnia and other aquatic invertebrates (Chronic 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
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#### Glycerine:

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**Biodegradability** : Result: Readily biodegradable.  
Biodegradation: 92 %  
Exposure time: 30 d  
Method: OECD Test Guideline 301D

### **Ivermectin:**

**Biodegradability** : Result: Not readily biodegradable.  
Biodegradation: 50 %  
Exposure time: 240 d

### **Ethanol:**

**Biodegradability** : Result: Readily biodegradable.  
Biodegradation: 84 %  
Exposure time: 20 d

### **Bioaccumulative potential**

#### **Components:**

##### **Propylene glycol:**

**Partition coefficient: n-octanol/water** : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

##### **Glycerine:**

**Partition coefficient: n-octanol/water** : log Pow: -1.75

##### **Ivermectin:**

**Bioaccumulation** : Bioconcentration factor (BCF): 74  
**Partition coefficient: n-octanol/water** : log Pow: 3.22

##### **Ethanol:**

**Partition coefficient: n-octanol/water** : log Pow: -0.35

### **Mobility in soil**

#### **Components:**

##### **Ethanol:**

**Distribution among environmental compartments** : log Koc: 0.2

### **Other adverse effects**

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

**Waste from residues** : Dispose of in accordance with local regulations.

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Contaminated packaging : Do not dispose of waste into sewer.  
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. (Ivermectin)  
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. (Ivermectin)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

##### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ivermectin)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### Domestic regulation

##### 49 CFR

UN/ID/NA number : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Ivermectin)  
Class : 9  
Packing group : III  
Labels : CLASS 9  
ERG Code : 171

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Marine pollutant : yes(Ivermectin)  
Remarks : Above applies only to containers over 119 gallons or 450 liters.  
Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

### 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

### CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Specific target organ toxicity (single or repeated exposure)

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### US State Regulations

#### Pennsylvania Right To Know

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
Water	7732-18-5
Propylene glycol	57-55-6
Glycerine	56-81-5
D-Glucitol	50-70-4
Sodium hydroxide	1310-73-2

#### California Permissible Exposure Limits for Chemical Contaminants

Glycerine	56-81-5
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#### The ingredients of this product are reported in the following inventories:

DSL	: not determined
AICS	: not determined
IECSC	: not determined

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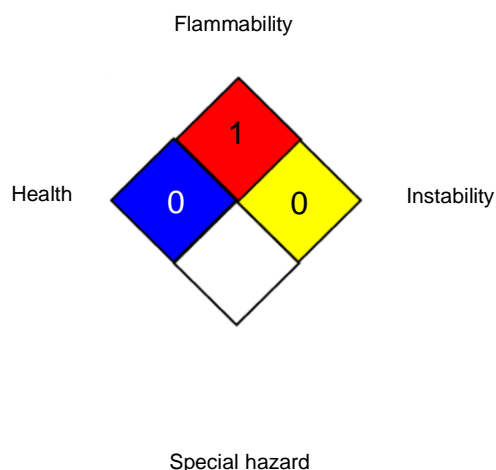
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### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

HEALTH	*	4
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL	: USA. NIOSH Recommended Exposure Limits
OSHA Z-1	: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
US WEEL	: USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / STEL	: Short-term exposure limit
NIOSH REL / TWA	: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-1 / TWA	: 8-hour time weighted average
US WEEL / TWA	: 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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 Pre-

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vention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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 Agency, <http://echa.europa.eu/>

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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

US / Z8