

Pyrantel Pamoate / Ivermectin Formulation

Version Revision Date: SDS Number: Date of last issue: 03/26/2022
3.4 04/09/2022 4892889-00008 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)

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 : **Prevention:**
 : 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.

Response:
P307 + P311 IF exposed: Call a doctor.

Storage:
P405 Store locked up.

Disposal:

Pyrantel Pamoate / Ivermectin Formulation

Version 3.4 Revision Date: 04/09/2022 SDS Number: 4892889-00008 Date of last issue: 03/26/2022
 Date of first issue: 09/17/2019

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	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	57-55-6	15
Glycerine	56-81-5	10
Ivermectin	70288-86-7	1.5
Ethanol#	64-17-5	0.1

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 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 when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
 Alcohol-resistant foam
 Carbon dioxide (CO₂)
 Dry chemical

Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.4	04/09/2022	4892889-00008	Date of first issue: 09/17/2019

- 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_x)
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 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 : 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

Pyrantel Pamoate / Ivermectin Formulation

Version 3.4 Revision Date: 04/09/2022 SDS Number: 4892889-00008 Date of last issue: 03/26/2022
 Date of first issue: 09/17/2019

- 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 ³ (OEB 2)	Internal
Propylene glycol	57-55-6	TWA	10 mg/m ³	US WEEL
Ivermectin	70288-86-7	TWA	0.3 mg/m ³ (OEB 3)	Internal
Further information: Skin				
		Wipe limit	300 mg/100 cm ²	Internal
Ethanol	64-17-5	STEL	1,000 ppm	ACGIH
		TWA	1,000 ppm 1,900 mg/m ³	NIOSH REL
		TWA	1,000 ppm 1,900 mg/m ³	OSHA Z-1

- 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

Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.4	04/09/2022	4892889-00008	Date of first issue: 09/17/2019

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
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

Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.4	04/09/2022	4892889-00008	Date of first issue: 09/17/2019

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
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.

Pyrantel Pamoate / Ivermectin Formulation

Version 3.4 Revision Date: 04/09/2022 SDS Number: 4892889-00008 Date of last issue: 03/26/2022
Date of first issue: 09/17/2019

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

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.

Pyrantel Pamoate / Ivermectin Formulation

Version 3.4 Revision Date: 04/09/2022 SDS Number: 4892889-00008 Date of last issue: 03/26/2022
Date of first issue: 09/17/2019

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): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124.7 mg/l
Exposure time: 4 h
Test atmosphere: vapor

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
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

Pyrantel Pamoate / Ivermectin Formulation

Version 3.4 Revision Date: 04/09/2022 SDS Number: 4892889-00008 Date of last issue: 03/26/2022
Date of first issue: 09/17/2019

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.

Ethanol:

Test Type : Local lymph node assay (LLNA)
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:

Pyrantel Pamoate / Ivermectin Formulation

Version 3.4 Revision Date: 04/09/2022 SDS Number: 4892889-00008 Date of last issue: 03/26/2022
Date of first issue: 09/17/2019

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

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

Ivermectin:

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

Test Type: DNA damage and repair, unscheduled DNA syn-
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: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal

Pyrantel Pamoate / Ivermectin Formulation

Version 3.4 Revision Date: 04/09/2022 SDS Number: 4892889-00008 Date of last issue: 03/26/2022
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

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
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.

Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.4	04/09/2022	4892889-00008	Date of first issue: 09/17/2019

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
 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.

Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.4	04/09/2022	4892889-00008	Date of first issue: 09/17/2019

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.

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

Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.4	04/09/2022	4892889-00008	Date of first issue: 09/17/2019

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
 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

Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.4	04/09/2022	4892889-00008	Date of first issue: 09/17/2019

Exposure time : 3 Months
 Target Organs : spleen, Bone marrow, Kidney

Ethanol:

Species : Rat
 NOAEL : 1,280 mg/kg
 LOAEL : 3,156 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

Ivermectin:

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

Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.4	04/09/2022	4892889-00008	Date of first issue: 09/17/2019

aquatic invertebrates (Chronic toxicity)
 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:

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)): > 1,000 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Ceriodaphnia* (water flea)): > 1,000 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 daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 9.6 mg/l
 Exposure time: 9 d

Toxicity to microorganisms : EC50 (*Pseudomonas putida*): 6,500 mg/l

Pyrantel Pamoate / Ivermectin Formulation

Version 3.4 Revision Date: 04/09/2022 SDS Number: 4892889-00008 Date of last issue: 03/26/2022
Date of first issue: 09/17/2019

Exposure time: 16 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

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

No data available

Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.4	04/09/2022	4892889-00008	Date of first issue: 09/17/2019

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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. (Ivermectin)
 Class : 9
 Packing group : III
 Labels : 9

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 Annex II of MARPOL 73/78 and the IBC Code

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.

Pyrantel Pamoate / Ivermectin Formulation

Version 3.4 Revision Date: 04/09/2022 SDS Number: 4892889-00008 Date of last issue: 03/26/2022
 Date of first issue: 09/17/2019

(Ivermectin)

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

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

DSL : not determined

AICS : not determined

Pyrantel Pamoate / Ivermectin Formulation

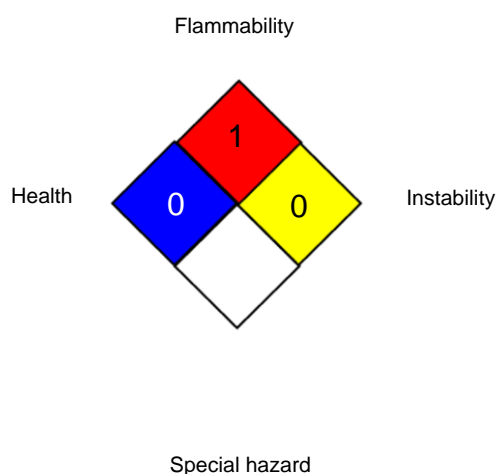
Version 3.4 Revision Date: 04/09/2022 SDS Number: 4892889-00008 Date of last issue: 03/26/2022
 Date of first issue: 09/17/2019

IECSC : not determined

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); EC_x - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL_x - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC_x - 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 Chemi-

Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03/26/2022
3.4	04/09/2022	4892889-00008	Date of first issue: 09/17/2019

icals 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; 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/>

Revision Date : 04/09/2022

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