SAFETY DATA SHEET

Pyrantel Pamoate / Ivermectin Formulation

SECTION 1. IDENTIFICATION

Product name: Pyrantel Pamoate / Ivermectin Formulation

Manufacturer or supplier's details

Company name of supplier: Merck & Co., Inc
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

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

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/ 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 POISON CENTER or doctor/ physician.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.
Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>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)</td>
<td>22204-24-6</td>
<td>38.3</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>15</td>
</tr>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>10</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>1.5</td>
</tr>
</tbody>
</table>

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

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 (NOx)
Sulfur oxides

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.

In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Discharge into the environment must be avoided.
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.

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

See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Use only with adequate ventilation.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Take care to prevent spills, waste and minimize release to the environment.

Keep in properly labeled containers.
Store locked up.
Store in accordance with the particular national regulations.
SAFETY DATA SHEET

Pyrantel Pamoate / Ivermectin Formulation

Version 2.0    Revision Date: 05/20/2020    SDS Number: 4892889-00003    Date of last issue: 03/23/2020

Date of first issue: 09/17/2019

Materials to avoid:

Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>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)</td>
<td>22204-24-6</td>
<td>TWA</td>
<td>250 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>TWA</td>
<td>0.05 mg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td>Wipe limit 0.5 mg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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
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
## SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

## 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): > 5,000 mg/kg

**Acute inhalation toxicity**:
- LC50 (Rabbit): > 159 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.

**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

Skin corrosion/irritation:
- Not classified based on available information.

Components:

**Propylene glycol:**
- **Species**: Rabbit
- **Method**: OECD Test Guideline 404
<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Result</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>Rabbit</td>
<td>No skin irritation</td>
<td></td>
</tr>
<tr>
<td>Ivermectin</td>
<td>Rabbit</td>
<td>No skin irritation</td>
<td></td>
</tr>
</tbody>
</table>

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components**:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Result</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Glycerine</td>
<td>Rabbit</td>
<td>No eye irritation</td>
<td></td>
</tr>
<tr>
<td>Ivermectin</td>
<td>Rabbit</td>
<td>Mild eye irritation</td>
<td></td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitization**

**Skin sensitization**
Not classified based on available information.

**Respiratory sensitization**
Not classified based on available information.

**Components**:

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Routes of exposure</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Maximization Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
</tr>
<tr>
<td>Ivermectin</td>
<td></td>
<td></td>
<td>Humans</td>
<td>Does not cause skin sensitization.</td>
</tr>
</tbody>
</table>
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
- 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 synthesis 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 synthesis in mammalian cells (in vitro) Test system: human diploid fibroblasts Result: negative
- Test Type: Mouse Lymphoma 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
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:


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.
  - 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.
SAFETY DATA SHEET

Pyrantel Pamoate / Ivermectin Formulation

**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):

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>Ingestion</td>
<td>10 mg/kg</td>
<td>30 mg/kg</td>
<td>3 d</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>NOAEL</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>Oral</td>
<td>600 mg/kg</td>
<td>19 d</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>NOAEL</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>Oral</td>
<td>600 mg/kg</td>
<td>30 d</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>NOAEL</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>Oral</td>
<td>600 mg/kg</td>
<td>90 d</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

**Propylene glycol:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, male</td>
<td>1,700 mg/kg</td>
</tr>
</tbody>
</table>
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Pyranetel Pamoate / Ivermectin Formulation

Version: 2.0
Revision Date: 05/20/2020
SDS Number: 4892889-00003
Date of last issue: 03/23/2020
Date of first issue: 09/17/2019

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

**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 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:

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

### 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

### Bioaccumulative potential

#### Components:

**Propylene glycol:**
- Partition coefficient: n-octanol/water: log Pow: -1.07

**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
Mobility in soil
No data available

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
Subsidiary risk : ENVIRONM.
Packing group : III
Labels : 9 (ENVIRONM.)
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
SAFETY DATA SHEET

Pyranthel Pamoate / Ivermectin Formulation

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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
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 un-packaged 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

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component RQ (lbs)</th>
<th>Calculated product RQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>1000</td>
<td>*</td>
</tr>
</tbody>
</table>

*: Calculated RQ exceeds reasonably attainable upper limit.

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-tetrahyd-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
- IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

**NFPA 704:**

- Health: 1
- Flammability: 0
- Instability: 0

**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

- US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
- US WEEL / TWA: 8-hr TWA

AICS - Australian Inventory of Chemical Substances; 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; 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
SAFETY DATA SHEET

Pyrantel Pamoate / Ivermectin Formulation

Version 2.0  Revision Date: 05/20/2020  SDS Number: 4892889-00003

Date of last issue: 03/23/2020  Date of first issue: 09/17/2019

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 05/20/2020

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