SAFETY DATA SHEET

Ivermectin / Pyrantel Formulation

SECTION 1. IDENTIFICATION

Product name: Ivermectin / Pyrantel 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)
Combustible dust

GHS label elements
Signal Word: Warning
Hazard Statements: If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

Other hazards
Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin.

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>8.6</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>4.6</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>0.02</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.
Get medical attention if symptoms occur.

In case of eye contact:
If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed:
If swallowed, DO NOT induce vomiting.
Get medical attention if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders:
No special precautions are necessary for first aid responders.

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 firefighting:
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides
Nitrogen oxides (NOx)
Sulfur oxides
Metal oxides
Chlorine compounds

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 firefighters:
Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
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.
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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:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- 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:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not breathe dust.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Inert or nuisance dust</th>
<th>50 Million particles per cubic foot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value type (Form of exposure): TWA (total dust)</td>
<td></td>
</tr>
<tr>
<td>Basis: OSHA Z-3</td>
<td></td>
</tr>
</tbody>
</table>

| 15 mg/m³ |
| Value type (Form of exposure): TWA (total dust) |
| Basis: OSHA Z-3 |

| 5 mg/m³ |
| Value type (Form of exposure): TWA (respirable fraction) |
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<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>30 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wipe limit</td>
<td></td>
<td>300 µg/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.
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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: powder

Color: brown

Odor: No data available

Odor Threshold: No data available

pH: 4 - 6 (68 °F / 20 °C) (as aqueous solution)

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): May form explosive dust-air mixture during processing, handling or other means.

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: log Pow: 3.22
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: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.
Conditions to avoid:
Heat, flames and sparks.
Avoid dust formation.
Incompatible materials:
Oxidizing agents
Hazardous decomposition products:
No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.
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Product:
Acute oral 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

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
Result : No skin irritation
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Ivermectin:
Species: Rabbit
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

Ivermectin:
Species: Rabbit
Result: Mild eye irritation

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.

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 \textit{in vitro}:
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Test Type: Chromosome aberration test \textit{in vitro}
  - Method: OECD Test Guideline 473
  - Result: negative

Genotoxicity \textit{in vivo}:
- Test Type: Mammalian erythrocyte micronucleus test (\textit{in vivo} cytogenetic assay)
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Result: negative

\textbf{Ivermectin}:

Genotoxicity \textit{in vitro}:
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Test Type: DNA damage and repair, unscheduled DNA synthesis \textit{in mammalian cells (in vitro)}
  - Test system: human diploid fibroblasts
  - Result: negative
- Test Type: Mouse Lymphoma
  - Result: negative

\textbf{Carcinogenicity}:
Not classified based on available information.

\textbf{Components}:

\textbf{Propylene glycol}:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 2 Years
- Result: negative

\textbf{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

\textbf{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.

\textbf{OSHA}:
No component of this product present at levels greater than or equal to 0.1% is
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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):

<table>
<thead>
<tr>
<th>Effects on fetal development</th>
<th>Test Type: Embryo-fetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 3,000 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: No effects on fertility and early embryonic development were detected.</td>
<td></td>
</tr>
</tbody>
</table>

| 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:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Two-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Mouse</td>
<td></td>
</tr>
<tr>
<td>Application Route: Ingestion</td>
<td></td>
</tr>
<tr>
<td>Result: negative</td>
<td></td>
</tr>
</tbody>
</table>

| Effects on fetal development | Test Type: Embryo-fetal development |
| Species: Mouse |
| Application Route: Ingestion |
| Result: negative |

Ivermectin:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td></td>
</tr>
<tr>
<td>Fertility: NOAEL: 0.6 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result: Animal testing did not show any effects on fertility.</td>
<td></td>
</tr>
</tbody>
</table>

| 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  

STOT-single exposure  
Not classified based on available information.

Components:

Ivermectin:

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central nervous system</td>
<td>Causes damage to organs.</td>
</tr>
</tbody>
</table>

STOT-repeated exposure  
Not classified based on available information.

Components:

Ivermectin:

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central nervous system</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Species</th>
</tr>
</thead>
</table>
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.0</td>
<td>04/04/2023</td>
<td>52652-00028</td>
<td>02/03/2023</td>
<td>02/02/2015</td>
</tr>
</tbody>
</table>

**NOAEL**

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

**Propylene glycol**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, male</td>
<td>&gt;= 1,700 mg/kg</td>
<td>Ingestion</td>
<td>2 y</td>
<td></td>
</tr>
</tbody>
</table>

**Ivermectin**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>0.5 mg/kg</td>
<td>1 mg/kg</td>
<td>Oral</td>
<td>14 Weeks</td>
<td>Central nervous system</td>
<td>Dilatation of the pupil, Tremors, Lack of coordination, anorexia</td>
</tr>
<tr>
<td>Monkey</td>
<td>1.2 mg/kg</td>
<td></td>
<td>Oral</td>
<td>2 Weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>0.4 mg/kg</td>
<td>0.8 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>spleen, Bone marrow, Kidney</td>
<td></td>
</tr>
</tbody>
</table>

**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):

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea, Headache, Dizziness, Fever</th>
</tr>
</thead>
</table>

**Ivermectin:**

<table>
<thead>
<tr>
<th>Skin contact</th>
<th>Remarks: Can be absorbed through skin.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>Remarks: May irritate eyes.</td>
</tr>
</tbody>
</table>
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:
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

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

Components:  
Propylene glycol:  
Biodegradability: Result: Readily biodegradable.  
Biodegradation: 98.3%  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  

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

Bioaccumulative potential  
Product:  
Bioaccumulation: Bioconcentration factor (BCF): 74  

Components:  
Propylene glycol:  
Partition coefficient: n-octanol/water: log Pow: -1.07  
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. Do not dispose of waste into sewer.
- 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
**SAFETY DATA SHEET**

**Ivermectin / Pyrantel Formulation**

<table>
<thead>
<tr>
<th>EmS Code</th>
<th>F-A, S-F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marine pollutant</td>
<td>yes</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th>UN/ID/NA number</th>
<th>UN 3077</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper shipping name</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Ivermectin)</td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
</tr>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>CLASS 9</td>
</tr>
<tr>
<td>ERG Code</td>
<td>171</td>
</tr>
<tr>
<td>Marine pollutant</td>
<td>yes(Ivermectin)</td>
</tr>
</tbody>
</table>

**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**

<table>
<thead>
<tr>
<th></th>
<th>Combustible dust</th>
</tr>
</thead>
</table>

**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**

| Soybean proteins | 9010-10-0 |
| 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 |
| D(+)-Glucose monohydrate | 5996-10-1 |
| Propylene glycol | 57-55-6 |
California Prop. 65
WARNING: This product can expose you to chemicals including tert-Butyl-4-methoxyphenol, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

The ingredients of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information
NFPA 704:

HMIS® IV:

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
CAL PEL: California permissible exposure limits for chemical contaminants (Title 8, Article 107)
OSHA Z-3: USA, Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
US WEEL: USA, Workplace Environmental Exposure Levels (WEEL)
CAL PEL / PEL: Permissible exposure limit
OSHA Z-3 / 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 Haz-
ardous 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; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; 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; 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


Revision Date: 04/04/2023

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.

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