SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Ivermectin / Pyrantel Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet
   Company : MSD
              Walton Manor, Walton
              MK7 7AJ Milton Keynes - United Kingdom
   Telephone : 908-740-4000
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :

   Signal word : Warning
   Hazard statements : H410 Very toxic to aquatic life with long lasting effects.
   Precautionary statements : Prevention:
                             P273 Avoid release to the environment.
Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 8.6%

2.3 Other hazards
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures
Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>244-837-1</td>
<td></td>
<td></td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>274-536-0</td>
<td></td>
<td>Acute Tox. 2; H300 Acute Tox. 3; H311 STOT SE 1; H370 (Central nervous system) STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 0.0025 - &lt; 0.025</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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

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.

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

4.3 Indication of any immediate medical attention and special treatment needed
Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture
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)
Sulphur oxides
Metal oxides
Chlorine compounds
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions
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.

6.3 Methods and material for containment and cleaning up
Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
- Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage:
- Do not store with the following product types:
  - Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s):
- No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<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></td>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (particles)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TWA (Total vapour and parti-</td>
<td>150 ppm 474 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>
### Safety Data Sheet

**Ivermectin / Pyrantel Formulation**

**Version:** 2.15  
**Revision Date:** 10.10.2020  
**SDS Number:** 52861-00018  
**Date of last issue:** 19.05.2020  
**Date of first issue:** 02.02.2015

---

**Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
</tr>
<tr>
<td>D-Glucono-1,5-lactone</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>59 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>11.9 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>14.6 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>5.9 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>5.9 mg/kg bw/day</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>2068.62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>2068.62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>295.52 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>443.28 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>443.28 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>126.65 mg/kg bw/day</td>
</tr>
</tbody>
</table>

**Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:**

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Substance</th>
<th>Marine water</th>
<th>Intermittent use/release</th>
<th>Sewage treatment plant</th>
<th>Fresh water sediment</th>
<th>Marine sediment</th>
<th>Soil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marine sediments</td>
<td>26 mg/l</td>
<td>183 mg/l</td>
<td>20000 mg/l</td>
<td>572 mg/kg</td>
<td>57.2 mg/kg</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>Synthetic organic compound</td>
<td>6.498 mg/l</td>
<td>0.36 mg/kg dry weight (d.w.)</td>
<td>0.36 mg/kg dry weight (d.w.)</td>
<td>0.014 mg/kg dry weight (d.w.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5 mg/l</td>
<td>500 mg/l</td>
<td>4.86 mg/kg dry weight (d.w.)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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

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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Skin and body protection

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.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143

Filter type: Particulates type (P)
9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Property Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>brown</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>4 - 6 (20 °C) as aqueous solution</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

9.2 Other information
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure: Inhalation, Skin contact, Ingestion, Eye contact

Acute 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):
Acute oral toxicity: LD50 (Rat): > 24,000 mg/kg
LD50 (Mouse): > 24,000 mg/kg
LD50 (Dog): 2,000 mg/kg

Ivermectin:
Acute oral toxicity: LD50 (Rat): 50 mg/kg
**Ivermectin / Pyrantel Formulation**

**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:**

**Ivermectin:**
- **Species:** Rabbit
- **Result:** No skin irritation

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

**Components:**

**Ivermectin:**
- **Species:** Rabbit
- **Result:** Mild eye irritation

**Respiratory or skin sensitisation**

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

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

**Components:**

**Ivermectin:**
- **Exposure routes:** Dermal
- **Species:** Humans
- **Result:** Does not cause skin sensitisation.

**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

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:

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

### 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 foetal development
- Test Type: Embryo-foetal 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-foetal development
- Species: Rabbit
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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>2.15</td>
<td>10.10.2020</td>
<td>52861-00018</td>
<td>19.05.2020</td>
<td>02.02.2015</td>
</tr>
</tbody>
</table>

**Application Route**: Oral

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

**Result**: No effects on fertility and early embryonic development were detected.

### 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 foetal 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**

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

### STOT - repeated exposure

Not classified based on available information.

#### Components:

**Ivermectin**

- **Target Organs**: Central nervous system
- **Assessment**: Causes damage to organs through prolonged or repeated
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>

Species: Dog
NOAEL: 600 mg/kg
Application Route: Oral
Exposure time: 19 d
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 600 mg/kg
Application Route: Oral
Exposure time: 30 d
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 600 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

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>
</tbody>
</table>

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, Diarrhoea, 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

12.1 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):

Ecotoxicology Assessment

Acute aquatic toxicity: Toxic effects cannot be excluded

Chronic aquatic toxicity: Toxic effects cannot be excluded

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
**12.2 Persistence and degradability**

**Components:**

**Ivermectin:**

Biodegradability: Result: Not readily biodegradable.

Biodegradation: 50 %

Exposure time: 240 d

**12.3 Bioaccumulative potential**

**Components:**

**Ivermectin:**

Bioaccumulation: Bioconcentration factor (BCF): 74

Partition coefficient: n-octanol/water: log Pow: 3.22

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

Not relevant

**12.6 Other adverse effects**

No data available

**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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**

**14.1 UN number**

ADN: UN 3077

ADR: UN 3077
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin / Pyrantel Formulation

Version 2.15 Revision Date: 10.10.2020 SDS Number: 52861-00018 Date of last issue: 19.05.2020
Date of first issue: 02.02.2015

RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ivermectin)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ivermectin)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ivermectin)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ivermectin)
IATA : Environmentally hazardous substance, solid, n.o.s. (Ivermectin)

14.3 Transport hazard class(es)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (·)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin / Pyrantel Formulation

Version 2.15
Revision Date: 10.10.2020
SDS Number: 52861-00018
Date of last issue: 19.05.2020
Date of first issue: 02.02.2015

Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that de-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Ivermectin / Pyrantel Formulation

Version 2.15  Revision Date: 10.10.2020  SDS Number: 52861-00018  Date of last issue: 19.05.2020

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

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-statements

- **H300**: Fatal if swallowed.
- **H311**: Toxic in contact with skin.
- **H370**: Causes damage to organs if swallowed.
- **H372**: Causes damage to organs through prolonged or repeated exposure if swallowed.
- **H400**: Very toxic to aquatic life.
- **H410**: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

- Acute Tox.: Acute toxicity
- Aquatic Acute: Short-term (acute) aquatic hazard
- Aquatic Chronic: Long-term (chronic) aquatic hazard
- STOT RE: Specific target organ toxicity - repeated exposure
- STOT SE: Specific target organ toxicity - single exposure
- GB EH40: UK. EH40 WEL - Workplace Exposure Limits
- GB EH40 / TWA: Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Con-
Further information


Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
</tr>
</tbody>
</table>

Classification procedure:

- Calculation method

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.

GB / EN