SAFETY DATA SHEET

Ivermectin / Pyrantel Formulation

Section 1: Identification

Product name : Ivermectin / Pyrantel Formulation

Manufacturer or supplier’s details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
          Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Section 2: Hazard identification

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
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

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>&lt; 10</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Ivermectin</td>
<td>70288-86-7</td>
<td>&lt; 1</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.
**SAFETY DATA SHEET**

**Ivermectin / Pyrantel Formulation**

<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>3.15</td>
<td>27.08.2021</td>
<td>52650-00019</td>
<td>10.10.2020</td>
<td>02.02.2015</td>
</tr>
</tbody>
</table>

- **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)
  - Sulphur 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.
- **Hazchem Code**: 2Z

**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. 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.

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.

Conditions for safe storage:
- Keep in properly labelled 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

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameter</th>
<th>Basis</th>
</tr>
</thead>
</table>

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**Section 9: Physical and chemical properties**

**Appearance**: powder

**Colour**: brown
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>Flammability (liquids)</td>
<td>No data available</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>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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

Exposure routes: 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

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

**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 sensitisation**

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

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

**Components:**

**Propylene glycol:**
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Ivermectin:  
Exposure routes: Dermal  
Species: Humans  
Result: Does not cause skin sensitisation.

Chronic toxicity  

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  
Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

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

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
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-naphtoic] 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
Application Route: Oral
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Propylene glycol:

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

Effects on foetal development:
Test Type: Embryo-foetal development
Species: Mouse
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 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 exposure.

Repeated dose toxicity

Components:

4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):
Species: Dog
NOAEL: 10 mg/kg
LOAEL: 30 mg/kg
Application Route: Ingestion
Exposure time: 3 d
Remarks: No significant adverse effects were reported

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

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

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

**Propylene glycol:**
Species: Rat, male
NOAEL: >= 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

**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, 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

**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**

**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

**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

- Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l
  Exposure time: 18 h

Date of last issue: 10.10.2020
Date of first issue: 02.02.2015
aquatic invertebrates: 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

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

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.
Section 14: Transport information

**International Regulations**

**UNRTDG**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ivermectin)
- Class: 9
- Packing group: III
- Labels: 9

**IATA-DGR**
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Ivermectin)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes

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

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**National Regulations**

**NZS 5433**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Ivermectin)
- Class: 9
- Packing group: III
- Labels: 9
- Hazchem Code: 2Z

**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.
Section 15: Regulatory information

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

HSNO Approval Number
HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

Section 16: Other information

Further information

Date format : dd.mm.yyyy

Full text of other abbreviations
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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 Law (Japan); ISO - International Or-
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.