1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Pyrantel Pamoate / Ivermectin Formulation

Supplier’s company name, address and phone number

Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Specific target organ toxicity - single exposure (Oral): Category 2 (Central nervous system)
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Central nervous system)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements

Hazard pictograms: 
Signal word: Warning
Hazard statements: H371 May cause damage to organs (Central nervous system) if swallowed. H373 May cause damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed. H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements: Prevention:
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.

Response:
P308 + P311 IF exposed or concerned: Call a POISON CENTER/doctor.
P391 Collect spillage.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 38.3%

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Mixture</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>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
</tr>
<tr>
<td></td>
<td>Ivermectin</td>
</tr>
<tr>
<td></td>
<td>Polyacrylic acid</td>
</tr>
<tr>
<td></td>
<td>Ethanol</td>
</tr>
</tbody>
</table>

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: May cause damage to organs if swallowed. May cause 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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: 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.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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 dis-
posal 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.

7. HANDLING AND STORAGE

**Handling**

**Technical measures**: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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

**Advice on safe handling**:
- Do not 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.

**Avoidance of contact**:
- Oxidizing agents

**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.

**Storage**

**Conditions for safe storage**:
- Keep in properly labelled containers.
- Store locked up.
- Store in accordance with the particular national regulations.

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

**Packaging material**:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Threshold limit value and permissible exposure limits for each component in the work environment**

<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>
</tbody>
</table>
Ivermectin | 70288-86-7 | TWA | 0.05 mg/m³ (OEB 3) | Internal
---|---|---|---|---
Further information: Skin
Wipe limit | 0.5 mg/100 cm² | Internal
Ethanol | 64-17-5 | STEL | 1,000 ppm | ACGIH

**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**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

- **Filter type**: Combined particulates and organic vapour type
- **Hand protection**: 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Physical state**: paste
- **Colour**: yellow
- **Odour**: No data available
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
- **Boiling point, initial boiling point and boiling range**: No data available
- **Flammability (solid, gas)**: Not applicable
SAFETY DATA SHEET

Pyrantel Pamoate / Ivermectin Formulation

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : Not applicable

Decomposition temperature : No data available

pH : No data available

Evaporation rate : Not applicable

Auto-ignition temperature : No data available

Viscosity
  Viscosity, kinematic : Not applicable

Solubility(ies)
  Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Density and / or relative density
  Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics
  Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.
11. TOXICOLOGICAL INFORMATION

Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

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: > 2,000 mg/kg
  - Method: Calculation method

- **Acute dermal toxicity**
  - Acute toxicity estimate: > 2,000 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

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

**Polyacrylic acid:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg

**Ethanol:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  - Method: OECD Test Guideline 401
- Acute inhalation toxicity: LC50 (Rat): 124.7 mg/l
  - Exposure time: 4 h
  - Test atmosphere: vapour

**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

**Polyacrylic acid:**
- Species: Rabbit
- Result: No skin irritation

**Ethanol:**
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation

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

**Components:**

**Propylene glycol:**
- Species: Rabbit
- Result: No eye irritation
- Method: OECD Test Guideline 405
Ivermectin:
Species: Rabbit
Result: Mild eye irritation

Polyacrylic acid:
Species: Rabbit
Result: No eye irritation

Ethanol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

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.

Ethanol:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-{2-(2-thienyl)vinyl}pyrimidine (1:1):
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Propylene glycol:
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

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

Ethanol:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

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

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

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-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  
- **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:** Three-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

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

**STOT - single exposure**  
May cause damage to organs (Central nervous system) if swallowed.

**Components:**

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

**STOT - repeated exposure**  
May cause damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

**Components:**

**Ivermectin:**  
Target Organs : Central nervous system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**4,4’-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):**

Species : Dog  
NOAEL : 10 mg/kg  
LOAEL : 30 mg/kg  
Application Route : Ingestion  
Exposure time : 3 d
Remarks : No significant adverse effects were reported

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

Species : Dog
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

Ethanol:
Species : Rat
NOAEL : 1,280 mg/kg
LOAEL : 3,156 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

4,4’-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):
Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, 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

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
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

M-Factor (Acute aquatic toxicity):
- 10,000

M-Factor (Chronic aquatic toxicity):
- 10,000

Polyacrylic acid:
Toxicity to fish:
- LC50 (Lepomis macrochirus (Bluegill sunfish)): 580 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50: > 100 mg/l
  Exposure time: 96 h

Ethanol:
Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l
  Exposure time: 48 h

Toxicity to algae/aquatic plants:
- ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l
  Exposure time: 72 h
- EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l
  Exposure time: 72 h
- NOEC (Daphnia magna (Water flea)): 9.6 mg/l
  Exposure time: 9 d

Toxicity to microorganisms:
- EC50 (Pseudomonas putida): 6,500 mg/l
  Exposure time: 16 h
Persistence and degradability

**Components:**

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

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

**Polyacrylic acid:**
Biodegradability: Result: Not readily biodegradable.
   Method: OECD Test Guideline 301

**Ethanol:**
Biodegradability: Result: Readily biodegradable.
   Biodegradation: 84 %
   Exposure time: 20 d

Bioaccumulative potential

**Components:**

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

**Ivermectin:**
Bioaccumulation: Bioconcentration factor (BCF): 74

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

Mobility in soil
No data available

Hazardous to the ozone layer
Not applicable

Other adverse effects
No data available
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.

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.

**National Regulations**

Refer to section 15 for specific national regulation.

**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.
15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
<tr>
<td>Acrylic acid polymer</td>
<td>234</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
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<tbody>
<tr>
<td>Ethanol</td>
<td>61</td>
<td>&gt;=0.1 - &lt;1</td>
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</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>61</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable
Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance (Category Z)
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd
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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