# SAFETY DATA SHEET

## Pyrantel Pamoate / Ivermectin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 2024/04/06 |
|---|---|---|---|
| 9.0 | 2024/09/28 | 4892884-00018 | Date of first issue: 2019/09/17 |

## 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

Restrictions on use : Not applicable

## 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

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|---|---|---|---|
| 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 | >= 30 - < 40 | - |
| Propylene glycol | 57-55-6 | >= 10 - < 20 | 2-234 |
| Ivermectin | 70288-86-7 | >= 1 - < 2.5 | - |
| Polyacrylic acid | 9003-01-4 | >= 0.1 - < 1 | 6-898 |
| Ethanol# | 64-17-5 | >= 0.1 - < 1 | 2-202 |

# Voluntarily-disclosed substance

## 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

| | | |
|---|---|---|
| | | vice immediately.<br>When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : | If inhaled, remove to fresh air.<br>Get medical attention if symptoms occur. |
| In case of skin contact | : | Wash with water and soap as a precaution.<br>Get medical attention if symptoms occur. |
| In case of eye contact | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists. |
| If swallowed | : | If swallowed, DO NOT induce vomiting unless directed to do so by medical personnel.<br>Get medical attention.<br>Rinse mouth thoroughly with water.<br>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.<br>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<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides<br>Nitrogen oxides (NOx)<br>Sulphur oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protec- | : | Use personal protective equipment. |

| | | |
|---|---|---|
| tive 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.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>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 breathe dust, fume, gas, mist, vapours or spray.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Do not eat, drink or smoke when using this product.<br>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.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use.<br>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**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Concentration standard / Permissible concentration | Basis |
|---|---|---|---|---|
| 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 | TWA | 250 µg/m3 (OEB 2) | Internal |
| Ivermectin | 70288-86-7 | TWA | 30 µg/m3 (OEB 3) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 300 µg/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

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a

| | | |
|---|---|---|
| | | potential for direct contact to the face with dusts, mists, or aerosols. |
| Skin and body protection | : | Work uniform or laboratory coat.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>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) | : | No data available |
| Flammability (liquids) | : | Not applicable |
| 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. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## 11. TOXICOLOGICAL INFORMATION

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

**Acute toxicity**

Not classified based on available information.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method |
| Acute dermal toxicity | : | Acute toxicity estimate: > 2,000 mg/kg<br>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<br><br>LD50 (Mouse): > 24,000 mg/kg<br><br>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<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg<br>Assessment: The substance or mixture has no acute dermal toxicity |

**Ivermectin:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 50 mg/kg<br><br>LD50 (Mouse): 25 mg/kg<br><br>LD50 (Monkey): > 24 mg/kg<br>Target Organs: Central nervous system<br>Symptoms: Vomiting, Dilatation of the pupil<br>Remarks: No mortality observed at this dose. |
| Acute inhalation toxicity | : | LC50 (Rat): 5.11 mg/l<br>Exposure time: 1 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): 406 mg/kg<br><br>LD50 (Rat): > 660 mg/kg |

**Polyacrylic acid:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Remarks: Based on data from similar materials |

**Ethanol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 10,470 mg/kg<br>Method: OECD Test Guideline 401 |
| Acute inhalation toxicity | : | LC50 (Rat, male): 116.9 mg/l<br>Exposure time: 4 h |

| | | |
|---|---|---|
| | | Test atmosphere: vapour |
| Acute dermal toxicity | : | LD50 (Rabbit): > 15,800 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 |

**Polyacrylic acid:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | No skin irritation |
| Remarks | : | Based on data from similar materials |

**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 |
| Remarks | : | Based on data from similar materials |

**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 | : | Mouse ear swelling test (MEST) |
| 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)<br>Result: negative |

**Propylene glycol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: negative |

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

**Ivermectin:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)<br>Test system: human diploid fibroblasts<br>Result: negative<br><br>Test Type: Mouse Lymphoma<br>Result: negative |

**Ethanol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative<br><br>Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Rat<br>Application Route: Ingestion<br>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-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<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 3,000 mg/kg body weight<br>Result: No effects on fertility and early embryonic development were detected.<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 1,000 mg/kg body weight<br>Result: No effects on fertility and early embryonic development were detected. |

**Propylene glycol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |

**Ivermectin:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility<br>Species: Rat<br>Application Route: Oral<br>Fertility: NOAEL: 0.6 mg/kg body weight<br>Result: Animal testing did not show any effects on fertility. |
| Effects on foetal develop- | : | Test Type: Development |

| | |
|---|---|
| ment | Species: Mouse<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 0.2 mg/kg body weight<br>Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses<br><br>Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 0.4 mg/kg body weight<br>Result: Embryotoxic effects and adverse effects on the off-spring were detected.<br>Remarks: The mechanism or mode of action may not be relevant in humans.<br><br>Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>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<br>Species: Mouse<br>Application Route: Ingestion<br>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 | : | 1,730 mg/kg |
| LOAEL | : | 3,200 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<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l<br>Exposure time: 7 d |
| Toxicity to microorganisms | : | NOEC (Pseudomonas putida): > 20,000 mg/l<br>Exposure time: 18 h |

**Ivermectin:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l<br>Exposure time: 96 h<br><br>LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 0.000025 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1 mg/l<br>Exposure time: 72 h<br>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 (Brachydanio rerio (zebrafish)): > 100 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: Based on data from similar materials |

| | | |
|---|---|---|
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): > 1 mg/l<br>Exposure time: 32 d<br>Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : | EC50 (activated sludge): > 100 mg/l<br>Exposure time: 3 h<br>Method: OECD Test Guideline 209<br>Remarks: Based on data from similar materials |

**Ethanol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l<br>Exposure time: 72 h<br><br>EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l<br>Exposure time: 72 h |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l<br>Exposure time: 100 d |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 9.6 mg/l<br>Exposure time: 9 d |
| Toxicity to microorganisms | : | EC50 (Protozoa): 5,800 mg/l<br>Exposure time: 4 h |

**Persistence and degradability**

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 98.3 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301F |

**Ivermectin:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 50 %<br>Exposure time: 240 d |

**Polyacrylic acid:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Remarks: Based on data from similar materials |

**Ethanol:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 84 %<br>Exposure time: 20 d |

**Bioaccumulative potential**

**Components:**

**Propylene glycol:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: -1.07<br>Method: Regulation (EC) No. 440/2008, Annex, A.8 |

**Ivermectin:**

| | | |
|---|---|---|
| Bioaccumulation | : | Bioconcentration factor (BCF): 74 |
| Partition coefficient: n-octanol/water | : | log Pow: 3.22 |

**Ethanol:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: -0.35 |

**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.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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.<br>(Ivermectin) |

| | | |
|---|---|---|
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Environmentally hazardous | : | yes |

**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**

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. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

**ERG Code** : 171

## 15. REGULATORY INFORMATION

**Related Regulations**

**Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Priority Assessment Chemical Substance

| Chemical name | Number |
|---|---|
| Propane-1,2-diol | 106 |

| | |
|---|---|
| Acrylic acid polymer | 234 |

**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)

| Chemical name | Concentration (%) | Remarks |
|---|---|---|
| Propylene glycol | >=10 - <20 | From April 1st, 2025 |
| Ethanol | >=0.1 - <1 | - |

**Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

| Chemical name | Remarks |
|---|---|
| Propylene glycol | From April 1st, 2025 |
| Ethanol | - |

**Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)**

Not applicable

**Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)**

Not applicable

**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 | : | Not classified as noxious liquid substance |
| 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

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

**Further information**

| | | |
|---|---|---|
| Sources of key data used to compile the Safety Data Sheet | : | Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/ |

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

Date format : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / STEL : Short-term exposure limit

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 Organisation for Standardization; KECI - 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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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