

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Ivermectin / Pyrantel Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 03.02.2025
5.1	14.04.2025	52866-00034	Date of first issue: 02.02.2015

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### 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 Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### 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.

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Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.

**Response:**  
P391 Collect spillage.

### 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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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)	22204-24-6 244-837-1		$\geq 1 - < 10$
Ivermectin	70288-86-7 274-536-0	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;	$\geq 0,0025 - < 0,025$

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		H400 Aquatic Chronic 1; H410	
		M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000	

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.<br>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.<br>Get medical attention if symptoms occur.   |
| In case of skin contact    | : | Wash with water and soap.<br>Get medical attention if symptoms occur.  |
| In case of eye contact     | : | If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.   |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>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.<br>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 |
|------------------------------|---|-------------|

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Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : 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 (NO<sub>x</sub>)  
Sulphur oxides  
Metal oxides  
Chlorine compounds

### 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 surfac-

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es, 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.<br>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.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<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. |

### 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:<br>Strong oxidizing agents                           |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

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### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

Dust      5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable dust)  
Basis: FOR-2011-12-06-1358

10 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (total dust)  
Basis: FOR-2011-12-06-1358

Components	CAS-No.	Value type (Form of exposure)	Control parameters	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/m <sup>3</sup> (OEB 2)	Internal
Propylene glycol	57-55-6	TWA	25 ppm 79 mg/m <sup>3</sup>	FOR-2011-12-06-1358
Ivermectin	70288-86-7	TWA	30 µg/m <sup>3</sup> (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	300 µg/100 cm <sup>2</sup>	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term systemic effects	168 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term local effects	10 mg/m <sup>3</sup>
	Consumers	Inhalation	Long-term systemic effects	50 mg/m <sup>3</sup>
D-Glucono-1,5-lactone	Workers	Inhalation	Long-term systemic effects	59 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	11,9 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	14,6 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	5,9 mg/kg bw/day

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	Consumers	Ingestion	Long-term systemic effects	5,9 mg/kg bw/day
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068,62 mg/m3
	Workers	Inhalation	Acute systemic effects	2068,62 mg/m3
	Workers	Skin contact	Long-term systemic effects	295,52 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	295,52 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	443,28 mg/m3
	Consumers	Inhalation	Acute systemic effects	443,28 mg/m3
	Consumers	Skin contact	Long-term systemic effects	126,65 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	126,65 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	126,65 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	126,65 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57,2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)
D-Glucono-1,5-lactone	Fresh water	0,1 mg/l
	Marine water	0,01 mg/l
	Intermittent use/release	1 mg/l
	Sewage treatment plant	6,498 mg/l
	Fresh water sediment	0,36 mg/kg dry weight (d.w.)
	Marine sediment	0,36 mg/kg dry weight (d.w.)
	Soil	0,014 mg/kg dry weight (d.w.)
Sodium chloride	Fresh water	5 mg/l
	Sewage treatment plant	500 mg/l
	Soil	4,86 mg/kg dry weight (d.w.)
Ivermectin	Fresh water	0,000004 mg/l
	Marine water	0,000004 mg/l

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### 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/face 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	:	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.
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 NS EN 143
Filter type	:	Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	brown
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.



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Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	4 - 6 (20 °C) (as aqueous solution)
Viscosity		
Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	Not applicable
Particle characteristics		
Particle size	:	No data available

### 9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	Not applicable
Molecular weight	:	No data available

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### 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 hazard classes as defined in Regulation (EC) No 1272/2008

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  
LD50 (Mouse): 25 mg/kg  
LD50 (Monkey): > 24 mg/kg

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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):**

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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  
Application Route: Oral  
Developmental Toxicity: NOAEL: 1.000 mg/kg body weight  
Result: No effects on fertility and early embryonic development

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ment 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 exposure.

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### 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

#### **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

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### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

Not classified based on available information.

### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

### 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

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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

### 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

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at



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levels of 0.1% or higher.

### 12.7 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. Do not dispose of waste into sewer.
Contaminated packaging	: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN	: UN 3077
ADR	: UN 3077
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)

Class	Subsidiary risks
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<b>ADN</b>	:	9
<b>ADR</b>	:	9
<b>RID</b>	:	9
<b>IMDG</b>	:	9
<b>IATA</b>	:	9

### 14.4 Packing group

<b>ADN</b>		
Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9

<b>ADR</b>		
Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9
Tunnel restriction code	:	(-)

<b>RID</b>		
Packing group	:	III
Classification Code	:	M7
Hazard Identification Number	:	90
Labels	:	9

<b>IMDG</b>		
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F

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

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

### 14.5 Environmental hazards

<b>ADN</b>		
Environmentally hazardous	:	yes

<b>ADR</b>		
Environmentally hazardous	:	yes

**RID**

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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 Maritime transport in bulk according to IMO instruments

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, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

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 (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

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E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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**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  
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits  
FOR-2011-12-06-1358 / TWA : Long term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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 - 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; 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 - Interna-

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tional 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECL - 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

### 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/>

### Classification of the mixture:

Aquatic Acute 1	H400
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
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.

NO / EN